Wyatt A. Lison (SBN – 316775)
wlison@fdpklaw.com
FEINSTEIN DOYLE PAYNE & KRAVEC, LLC
429 Fourth Avenue, Suite 1300
Pittsburgh, PA 15219
Tel.: (412) 281-8400
Fax: (412) 281-1007

John Peter Zavez (admitted *pro hac vice*)
jzavez@akzlaw.com
ADKINS, KELSTON & ZAVEZ, P.C.
90 Canal Street, Suite 120
Boston, MA 02114
Telephone: (617) 367-1040
Facsimile: (617) 742-8280

J. Benjamin Blakeman (SBN - 60596)
BLAKEMAN LAW
8383 Wilshire Boulevard, Suite 510
Beverly Hills, CA 90211
Telephone: (213) 629-9922
Email: ben@lifeinsurance-law.com

ATTORNEYS FOR PLAINTIFFS

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CHRISTINA LABAJO, HOWARD CLARK, and BERRY SAIZON

Plaintiffs,

vs.

GENERAL NUTRITION CORPORATION and DOES 1-100,

Defendants.

Case No.: 4:19-cv-01984-HSG

STIPULATION AND ORDER ALLOWING PLAINTIFFS TO FILE FIRST AMENDED COMPLAINT

Pursuant to Fed. R. Civ. P. 15(a)(2), Plaintiffs Christina Labajo, Howard Clark, and Berry Sazon (collectively, "Plaintiffs"), and Defendant General Nutrition Corporation ("Defendant" or "GNC") (collectively, the "Parties"), hereby Stipulate that Plaintiffs should be granted leave to amend to file their First Amended Complaint, a copy of which is attached hereto as Exhibit A.

RECITALS

WHEREAS, on March 12, 2019, Plaintiffs filed a Complaint in the Superior Court of the State of California for the County of San Francisco, Case No. CGC-19-574459;

WHEREAS, on April 12, 2019, Defendant filed a Notice of Removal of Plaintiffs' lawsuit pursuant to 28 U.S.C. §§ 1332, 1441, and 1446 (Dkt. No. 1);

WHEREAS, on November 25, 2019, GNC gave Plaintiffs its written consent to file the First Amended Complaint; and,

WHEREAS, on August 21, 2019, the Court entered a Scheduling Order permitting the parties to amend pleadings until November 30, 2019 (Dkt. No. 20).

STIPULATION

Based upon the above recitals, the Parties, through their undersigned counsel, hereby stipulate as follows:

1. Plaintiffs should be granted leave to amend to file their First Amended Complaint, a copy of which is attached hereto as Exhibit A.

Dated: November 26, 2019

FEINSTEIN DOYLE PAYNE & KRAVEC, LLC

By: /s/ *Wyatt A. Lison*
Wyatt A. Lison
Attorneys for Plaintiffs
Christina Labajo, Howard Clark, and
Berry Saizon

Dated: November 26, 2019

COZEN O'CONNOR

By: */s/ Andrew M. Hutchison*
Andrew M. Hutchison
Attorneys for Defendant
General Nutrition Corporation

PURSUANT TO STIPULATION, IT IS SO ORDERED.

Dated: November 27, 2019

Honorable Haywood S. Gilliam, Jr.
United States District Judge
Northern District of California

EXHIBIT A

Wyatt A. Lison (SBN – 316775)
wlison@fdpklaw.com
FEINSTEIN DOYLE PAYNE & KRAVEC, LLC
429 Fourth Avenue, Suite 1300
Pittsburgh, PA 15219
Tel.: (412) 281-8400
Fax: (412) 281-1007

John Peter Zavez (admitted *pro hac vice*)
jzavez@akzlaw.com
ADKINS, KELSTON & ZAVEZ, P.C.
90 Canal Street, Suite 120
Boston, MA 02114
Telephone: (617) 367-1040
Facsimile: (617) 742-8280

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BLAKEMAN LAW
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Beverly Hills, CA 90211
Telephone: (213) 629-9922
Email: ben@lifeinsurance-law.com

ATTORNEYS FOR PLAINTIFFS

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CHRISTINA LABAJO, HOWARD CLARK, and BERRY SAIZON **Plaintiffs,** **v.** **GENERAL NUTRITION CORPORATION and DOES 1-100** **Defendants.**	**CASE NO.: 3:19-cv-01984-HSG** **FIRST AMENDED COMPLAINT FOR:** **(1) Violation of the Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.*** **DEMAND FOR JURY TRIAL**

Plaintiffs Christina Labajo, Howard Clark and Berry Saizon (collectively Plaintiffs), by and through their attorneys, bring this action against Defendant General Nutrition Corporation ("GNC"), and allege as follows based upon their personal experiences as to their own acts and status, and based upon the investigation of their counsel, and information and belief as to all other matters:

NATURE OF THE CASE

1. This is an action primarily seeking declaratory and injunctive relief to restrain GNC from selling dietary supplements mislabeled with unlawful disease claims in California, commonly referred to as "Health Fraud" by federal food and drug regulators (hereinafter the "Products[1]").

2. As explained herein, the U.S. Food and Drug Administration ("FDA"), after a deliberative process and in its final rule in implementing regulations defining the use of structure/function claims on dietary supplements, determined that supplements cannot expressly or impliedly claim to lower cholesterol because it implies treatment for coronary heart disease, rendering the claim misleading and making the product classified as a drug subject to pre-approval based on safety and efficacy. Despite the misleading nature of cholesterol claims on supplements, GNC labels five supplements as being able to maintain and/or support normal or healthy cholesterol levels, without clarifying that they cannot lower cholesterol by stating that they may only maintain cholesterol levels that are already within a normal range, which FDA has said is necessary to avoid implying treatment for hypercholesterolemia and coronary heart disease.

3. Similarly, after the same deliberative process and within the same final rule, FDA determined that dietary supplements cannot expressly or impliedly claim to build, strengthen or maintain bones in menopausal women because it misleadingly implies treatment for osteoporosis, a condition typically experienced by women who have gone through menopause and makes the product a drug subject to pre-approval based on safety and efficacy. Yet, GNC labels three supplements targeted towards menopausal women as able to help build, support, and/or maintain bones.

[1] The term Products used herein refers to GNC Healthy Cholesterol Formula (Exhibit 1), GNC Policosanol (Exhibit 2), GNC Ultra 35 Probiotic Complex with Cholesterol Support (Exhibit 3), GNC Probiotic Solutions Adult 50 Plus (Exhibit 4), GNC Women's Ultra Mega 50 Plus Vitapak (Exhibit 5), GNC Women's Ultra Mega Menopause Vitapak (Exhibit 6), and GNC Women's Ultra Mega 50 Plus (Exhibit 7).

4. The labeling of GNC's Products as being able to cure, treat, mitigate or prevent hypercholesterolemia, coronary heart disease, and/or osteoporosis in menopausal women is both unlawful, it is also a "Health Fraud" because GNC's Products have not been approved as safe and effective for these intended purposes. Under the U.S. Food, Drug and Cosmetic Act ("FDCA") and identical provisions in California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875, *et seq* ("Sherman Law"), products that claim to cure, treat, mitigate or prevent diseases or conditions like hypercholesterolemia, coronary heart disease and osteoporosis are defined as drugs. Sherman Law § 109925 and FDCA § 201(g)(1). Drugs may not be manufactured, labeled or sold without prior approval of FDA. 21 U.S.C. §§ 331(d) and 355(a); Sherman Law § 111550. In violation of these laws, GNC's Products shown in Exhibits 1-7 are labeled to cure, treat, mitigate or prevent hypercholesterolemia (i.e., high cholesterol), coronary heart disease, and/or osteoporosis without prior FDA approval. This identical conduct serves as the sole factual basis of each state law cause of action brought by this Complaint, and Plaintiffs do not seek to enforce any of the state law claims raised herein to impose any standard of conduct that exceeds that which would violate the FDCA and regulations adopted pursuant thereto. Thus, Plaintiffs' state law claims are not preempted by the FDCA because Plaintiffs' claims for state law violations seek to enforce the same standard of conduct required by federal law and Plaintiffs' state law claims are based upon GNC's breach of that standard of conduct. For any of Plaintiffs' state law causes of action, the allegations supporting those causes of action and any forms of relief sought for those state law causes of action, Plaintiffs expressly disclaim any attempt to hold GNC to a higher standard of conduct than what is required under federal law, and do not seek any form of relief based on conduct exceeding that which is required under federal law. All state law causes of action asserted in this Complaint, the allegations supporting those state law causes of action asserted herein and any forms of relief sought for those state law causes of action asserted herein shall be read consistent with the limitations set forth in this paragraph.

5. Accordingly, Plaintiffs bring this action pursuant to Bus. & Prof. Code § 17203 to enjoin GNC from continuing to sell dietary supplements California labeled with the unlawful disease or treatment claims alleged throughout this Complaint.

JURISDICTION AND VENUE

6. Plaintiffs filed their case in the Superior Court of California, for the County of San Francisco, asserting jurisdiction and venue pursuant to Cal. Civ. Code §§ 395.5, 410.10 and 1780(d) over the claims raised in this Complaint for the following reasons: (i) GNC regularly sells, advertises, markets and/or distributes the Products in San Francisco County and throughout the State of California; (ii) a substantial portion of the underlying transactions and events complained of herein occurred in, and Plaintiff Clark resides in, San Francisco County; and (iii) Plaintiff Clark is a citizen and resident of California who resides in San Francisco County and purchased GNC's Products in San Francisco County. Attached hereto as Exhibit 8 is a declaration in compliance with Cal. Civ. Code § 1780(d). GNC removed Plaintiffs' case on April 12, 2019 based on diversity jurisdiction under 21 U.S.C. § 1332(a)(1), asserting complete diversity exists between Plaintiffs and GNC, and the amount in controversy satisfies 28 U.S.C. § 1332(a). *See* Doc. No. 1.

THE PARTIES

7. Plaintiff Christina Labajo is a citizen of the State of California and a resident of San Bernardino County, California. In or around March 2017, Ms. Labajo purchased at least one of GNC's Women's Ultra Mega Menopause Vitapak product from GNC stores in San Bernardino County, California, and paid around $45.00 for the product. The GNC Women's Ultra Mega Menopause Vitapak Ms. Labajo purchased specifically indicated it was a "Menopause Formula" with ingredients that "act as mild estrogens." The GNC Women's Ultra Mega Menopause Vitapak product Ms. Labajo purchased was also labeled as being a clinically studied multivitamin, as being able to "help[] build and maintain bone density," and as containing a formula of vitamins and minerals "shown to support natural bone building." The GNC Women's Ultra Mega Menopause Vitapak product Ms. Labajo purchased was also labeled as supporting "heart and cholesterol health," as providing support "for cardiovascular system function," and "healthy blood lipid levels." Ms. Labajo purchased GNC's products relying, in part, on these labeling statements made on the product's label believing the product was lawfully marketed to cure, treat, prevent or mitigate osteoporosis and coronary heart disease, and more effective than other similar dietary supplements sold by other manufacturers that were not labeled to help treat, prevent or mitigate osteoporosis or coronary heart disease. Had the

GNC product that Ms. Labajo purchased not stated or implied that they could help cure, treat, prevent or mitigate osteoporosis and coronary heart disease, this would have affected Ms. Labajo's purchasing decisions in that she either would not have purchased the GNC product, she would not have been willing to pay the price she did for the GNC product, she would have purchased a lesser quantity of the GNC product, she would have purchased another dietary supplement product, or she would have purchased a similar dietary supplement that was less expensive.

8. Plaintiff Howard Clark is a citizen of the State of California and a resident of San Francisco County, California. Between July 2016 and February 2017, Mr. Clark purchased at least the following GNC dietary supplements: GNC Healthy Cholesterol Formula, GNC Probiotic Solutions Adults 50 Plus and GNC Ultra 35 Probiotic Complex with Cholesterol Support. Mr. Clark purchased these products from GNC stores in San Francisco County, California and paid between $9.00 and $40.00 for each of the products purchased. The Healthy Cholesterol Formula product Mr. Clark purchased was prominently labeled as able to "support[] normal, healthy cholesterol & triglyceride levels with clinically studied black tea extract." The Probiotic Solutions Adults 50 Plus product that Mr. Clark purchased was prominently labeled as "support[ing] healthy cholesterol & vitamin D levels." The Ultra 35 Probiotic Complex that Mr. Clark purchased was prominently labeled as "[c]linically studied support for healthy cholesterol levels," which is reinforced on the back label which states the product contains "[s]pecialized probiotic strains for cholesterol support." Mr. Clark purchased GNC's products relying, in part, on the above-identified labeling statements made on the products' labels believing they were lawfully marketed to help lower his cholesterol level, and thereby help cure, treat, prevent or mitigate coronary heart disease, and more effective than other similar dietary supplements sold by other manufacturers that were not labeled to help lower cholesterol level. Had the GNC products that Mr. Clark purchased not stated or implied that they could help lower his cholesterol level, this would have affected Mr. Clark's purchasing decisions in that he either would not have purchased the GNC products, he would not have been willing to pay the price he did for the GNC products, he would have purchased a lesser quantity of the GNC product, he would have purchased other dietary supplement products, or he would have purchased a similar dietary supplement that was less expensive.

9. Plaintiff Berry Saizon is a citizen of the State of California and a resident of Los Angeles County, California. Between October 2017 and February 2018, Mr. Saizon purchased at least the following GNC dietary supplements: GNC Healthy Cholesterol Formula and GNC Probiotic Solutions Adults 50 Plus. Mr. Saizon purchased these products from GNC stores in Los Angeles County, California and paid around $20.00 for the GNC Healthy Cholesterol Formula and around $40.00 for the GNC Probiotic Solutions Adults 50 Plus. The GNC Healthy Cholesterol Formula Mr. Saizon purchased was prominently labeled as able to "support[] normal, healthy cholesterol & triglyceride levels with clinically studied black tea extract." The GNC Probiotic Solutions Adults 50 Plus that Mr. Saizon product was prominently labeled as "support[ing] healthy cholesterol & vitamin D levels." Mr. Saizon purchased GNC's products relying, in part, on the above-identified labeling statements made on the products' labels believing they were lawfully marketed to help lower his cholesterol level, and thereby help cure, treat, prevent or mitigate coronary heart disease, and more effective than other similar dietary supplements sold by other manufacturers that were not labeled to help lower cholesterol level. Had the GNC products that Mr. Saizon purchased not stated or implied that they could help lower his cholesterol level, this would have affected Mr. Saizon's purchasing decisions in that he either would not have purchased the GNC products, he would not have been willing to pay the price he did for the GNC products, he would have purchased a lesser quantity of the GNC product, he would have purchased other dietary supplement products, or he would have purchased a similar dietary supplement that was less expensive.

10. General Nutrition Corporation is a corporation organized under the law of the Commonwealth of Pennsylvania. General Nutrition Corporation is the successor-by-merger of GNC Franchising, LLC, a Pennsylvania corporation. General Nutrition Corporation's principal place of business is located at 300 Sixth Street, Pittsburgh, Pennsylvania 15222. General Nutrition Corporation is a health and wellness company that sells various nutritional supplements and vitamins throughout the country. General Nutrition Corporation is identified as the "Distributor" of the Products at issue in this lawsuit. *See* Exhibits 1-7.

11. Defendants Does 1 to 100, inclusive, are sued under fictitious names pursuant to Code of Civil Procedure section 474. Plaintiffs allege, based on information and belief, that each of the

defendants sued under fictitious names is in some manner responsible for the wrongs and damages alleged below, in so acting was functioning as the agent, servant, partner, and employee of General Nutrition Corporation, and in taking the actions mentioned below was acting within the course and scope of his or her authority as such agent, servant, partner, and employee, with the permission and consent of General Nutrition Corporation or other Doe co-defendants.

FACTUAL ALLEGATIONS

BACKGROUND OF DRUG AND DIETARY SUPPLEMENT LAWS AND REGULATIONS

12. The purpose of food and drug laws, including the FDCA, FDA regulations and the Sherman Law, is consumer protection. These laws and regulations were enacted, in part, to prohibit the sale of misbranded food and drugs.

13. Amongst other things, the FDCA and Sherman Law require companies wishing to sell a "drug," defined as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal," to prove to the FDA that it is safe and effective prior to marketing it. 21 U.S.C. § 321(g)(1)(B); Sherman Law § 109925(b).

14. To be proven safe and effective as a new drug, drug companies must first test it and send FDA's Center for Drug Evaluation and Research ("CDER") the evidence from these tests to prove the drug is safe and effective for its intended use. A team of CDER physicians, statisticians, chemists, pharmacologist, and other scientists review the company's data and proposed labeling to determine whether the drug's health benefits outweigh its known risks.[2]

15. It is a violation of federal and California law to sell a new drug without prior approval by FDA. 21 U.S.C. § 355(a); Sherman Law § 111550.

16. A dietary supplement, unlike a drug, is a food intended to supplement the diet that bears or contains a dietary ingredient such as a vitamin, mineral, herb or other botanical, or amino acid. 21 U.S.C. § 321(ff).

[2] *See* FDA "How Drugs are Developed and Approved" available online at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm.

17. Foods, including dietary supplements, are misbranded if they characterize the relationship of a nutrient to a disease or health-related condition unless made in accordance with the FDCA. 21 U.S.C. § 343(r)(1); Sherman Law § 110670.

18. A statement characterizing the relationship of a nutrient to a disease or health-related condition on a dietary supplement may be made only if, "the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A).

19. A description of the role of a nutrient or dietary ingredient intended to affect the structure or function in humans is commonly referred to as "structure/function" claims. A structure/function claim may only be made if "the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading." *Id*. § 343(r)(6)(B).

20. Importantly, a dietary supplement may not explicitly or implicitly claim to diagnose, cure, mitigate, treat, or prevent a specific disease or class of diseases. 21 U.S.C. § 343(r)(6)(C). For purposes of this law, a "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly (*e.g.,* cardiovascular disease), or a state of health leading to such dysfunctioning (*e.g*., hypertension); except that diseases resulting from essential nutrient deficiencies (*e.g*., scurvy, pellagra) are not included in this definition. 21 C.F.R. 101.93(g).

21. Pursuant to 21 C.F.R. § 101.93(g)(2), a statement on a dietary supplement claims to diagnose, cure, mitigate, treat, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

(iv) Has an effect on a disease or diseases through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;

(C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;

(D) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or

(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(x) Otherwise suggests an effect on a disease or diseases.

22. Claims that a product can cure, mitigate, treat, or prevent a disease require prior approval by the FDA and may be made only for products that are approved drug products, or for foods with FDA-approved "health claims." 21 U.S.C. § 355(a) (drugs); 21 C.F.R. 101.93 (f) (food). Failure to obtain prior FDA approval of such a claim in either case renders the claim illegal in violation of 21 C.F.R. 101.93 (f) if a food, or 21 U.S.C. § 355(a) if a drug.

23. The promotion, advertisement, distribution or sale of substances represented as being effective to diagnose, cure, mitigate, treat, or prevent disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven to and approved by the FDA as safe and effective for such purposes, is called "Health Fraud." FDA Compliance Policy Guide 120.500 Health Fraud.[3]

24. FDA classifies Health Fraud as a "major economic cheat" even when a person's health is not directly at risk. *Id.*

25. Even if a Health Fraud does not pose a direct risk to a person's health, it can be an indirect health risk when a person relies on a Health Fraud in delaying or discontinuing appropriate medical treatment. *Id*.

GNC'S HEALTH FRAUD

26. GNC sells several products which explicitly or impliedly claim to treat, cure, prevent or mitigate hypercholesterolemia, coronary heart disease and/or osteoporosis without being approved by FDA as being safe or effective for these purposes. Although the products are labeled to treat, cure, prevent or mitigate these diseases or conditions, the products have not been scientifically proven to and approved by the FDA as safe or effective at mitigating, treating, curing or preventing any disease or condition. Accordingly, GNC's products described below are Health Frauds.

Products Claimed to Cure, Mitigate, Treat or Prevent Hypercholesterolemia and Coronary Heart Disease

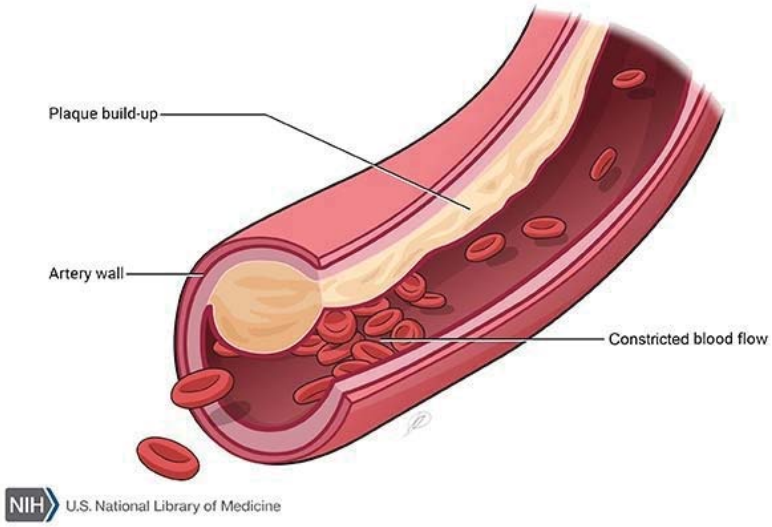
27. Hypercholesterolemia is a condition characterized by high levels of cholesterol in the blood. While the body needs cholesterol to build cell membranes and make certain hormones, too much cholesterol increases a person's risk of developing heart disease and stroke.[4]

28. People with hypercholesterolemia, *i.e.*, high cholesterol levels, have a high risk of developing coronary artery disease. This occurs when excess cholesterol in the bloodstream is deposited in the walls of blood vessels, particularly in the arteries that supply blood to the heart

[3] Available online at https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073838.htm.

[4] *See* https://www.nhlbi.nih.gov/health-topics/high-blood-cholesterol.

(coronary arteries). *See* picture below from the U.S. National Institutes of Health. The abnormal cholesterol buildup forms clumps called plaque that narrow and harden artery walls. As the plaque



gets bigger, it can clog the arteries and restrict the flow of blood to the heart. If too much cholesterol builds up, the blood cannot flow through to the heart which can cause a heart attack.

29. Due to the seriousness consequences of hypercholesterolemia, and the many health and concomitant medication considerations that go into its treatment, hypercholesterolemia is not amenable to self-diagnosis and treatment, meaning adequate directions for use cannot be written so that a layperson can use a product intended to treat hypercholesterolemia safely.[5] FDA has not approved over-the-counter medicines to treat hypercholesterolemia, and instructs consumers to consult their physicians about medicines to help treat the condition.[6] GNC's products described herein have not been approved by FDA as safe and effective for treatment of hypercholesterolemia. Any claim that a dietary supplement can treat, cure, prevent or mitigate hypercholesterolemia or coronary heart disease is a drug claim, and a Health Fraud as it has not been approved by FDA.

30. After the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), which established regulatory requirements and procedures for structure/function claims,

[5] *See, e.g.,* FDA Warning Letter to Multimmunity, Inc. dated September 25, 2014 available online at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm417431.htm.

[6] *See* FDA, High Cholesterol -- Medicines To Help You available online at https://www.fda.gov/ForConsumers/ByAudience/ucm118595.htm.

FDA took public comments and issued regulations to help delineate what would be lawful structure/function claims, and unlawful drug claims. *See* Final Rule on the Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000-01 (Jan. 6, 2000) (to be codified at 21 C.F.R. Part 101) (hereinafter, "Final Rule"). This included claims on dietary supplement regarding cholesterol levels. *Id*. at 1015-19.

31. FDA has long acknowledged that many people think of cholesterol solely in terms of the negative role of high cholesterol and heart disease. Information readily available to consumers on the internet advises of the link between high cholesterol and coronary heart disease.[7]

32. Due to consumer perception linking high cholesterol with heart disease, the availability of information discussing the association between high cholesterol levels and coronary heart disease, the serious health consequences resulting from hypercholesterolemia, and the need for professional advice to treat hypercholesterolemia, FDA undertook careful consideration and deliberation in determining what might be considered an acceptable structure/function claim for cholesterol levels made in the labeling of dietary supplements, and what would be considered an unlawful disease claim prohibited by 21 C.F.R. § 101.93. *See* Final Rule at 1015-18.

33. FDA acknowledged that references in dietary supplement labeling to physiologic markers or symptoms of a disease that are quantifiably linked to that disease in an official government health agency summary statement or consensus report, such as high cholesterol and coronary heart disease, would be appropriately treated as implied disease claims. Final Rule at 1018. FDA specifically noted that hypercholesterolemia is not just a physiologic marker for coronary heart disease, but is a disease condition itself. *Id*.

34. Thus, any claim that a dietary supplement can lower cholesterol, explicit or implicit, is an unlawful drug claim and not a permissible structure/function claim. Final Rule at 1019. FDA

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[7] *See, e.g.*, "What causes high cholesterol?" available at https://www.medicalnewstoday.com/articles/9152.php; "High cholesterol" available a t https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/symptoms-causes/syc-20350800; and "High Cholesterol Risk Factors: available at https://www.webmd.com/cholesterol-management/high-cholesterol-risk-factors.

determined this despite the then U.S. Surgeon General advocating for the ability of dietary supplements to be marketed for lowering cholesterol due to the prevalence of heart disease. *Id*. FDA concluded that claiming a dietary supplement can lower cholesterol is prohibited because the use of ineffective therapies in persons with elevated cholesterol, which can delay or prevent effective treatment, itself poses significant public health risks. *Id*.

35. Even though an explicit or implicit claim that a dietary supplement can lower cholesterol is an unlawful disease claim because elevated cholesterol level is a sign of hypercholesterolemia and an important risk factor for heart disease, having cholesterol within the normal range is not a sign or risk factor of disease.

36. Due to the tension between consumer understanding of the link between high cholesterol levels and heart disease, and the recognition that normal cholesterol levels are important, to ensure that a dietary supplement's label does not misleadingly imply the ability to cure, mitigate, treat or prevent high cholesterol, FDA determined that claims linking a substance and cholesterol level must make clear that it can only support or maintain cholesterol levels for people whose cholesterol levels are already in a normal range. Final Rule at 1018-19.

37. FDA also considered whether maintaining "healthy cholesterol" levels would be an acceptable structure/function claim. Final Rule at 1015. Many consumers understand there is a difference between high-density lipoprotein, often called the "good cholesterol" and low-density lipoprotein, often called "bad cholesterol."[8] Given this understanding, FDA determined that references to "healthy cholesterol" could be misleading as this term often refers to high density lipoproteins which are believed to be beneficial. *Id*. at 1019.

38. FDA thus rejected comments suggesting that a dietary supplement labeled as supporting "normal" or "healthy" cholesterol levels does not imply treatment for hypercholesterolemia and coronary heart disease, because it implies lowering "bad cholesterol," or helping with "good cholesterol." Final Rule at 1018-19. The example FDA gave of an acceptable structure function claim for cholesterol that would not misleadingly suggest lowering "bad" cholesterol, or raising "good"

[8] *See* https://www.cdc.gov/cholesterol/ldl_hdl.htm.

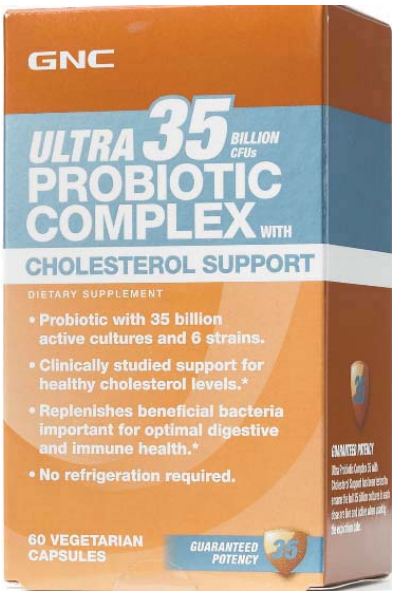
cholesterol is, "helps to maintain cholesterol levels that are already within the normal range." *Id*. at 1019.

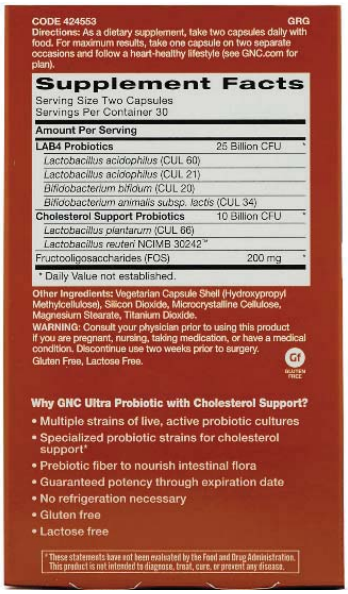
39. Despite FDA's clear guidance that any claim on a dietary supplement about cholesterol level must make it clear that it can only help maintain or support cholesterol levels that are already within the normal range so that it is not implying that it can help cure, treat, prevent or mitigate hypercholesterolemia and/or coronary heart disease, GNC sells several dietary supplements implying that they can help lower "bad" cholesterol levels, or raise "good" cholesterol levels, because they state they can support healthy or normal cholesterol levels as shown and described below.

40. GNC Healthy Cholesterol Formula (Exhibit 1), Policosanol (Exhibit 2), Ultra 35 Probiotic Complex with Cholesterol Support (Exhibit 3), Probiotic Solutions Adults 50 Plus (Exhibit 4), Women's Ultra Mega 50 Plus Vitapak (Exhibit 5), and GNC's Women's Ultra Mega Menopause Vitapak (Exhibit 6) each implicitly claim to cure, mitigate, treat, or prevent hypercholesterolemia.

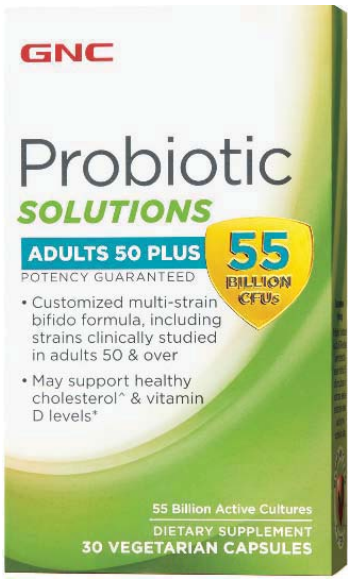
41. As shown above, GNC's "Healthy Cholesterol Formula" is labeled as being a "PHYSICIAN FORMULATED NUTRITION SOLUTION[]" that "[s]upports normal, healthy cholesterol & triglyceride levels with clinically studied black tea extracts." Exhibit 1. The product's name itself, "Healthy Cholesterol Formula," has been found misleading by FDA as referring to high density lipoproteins, or "good cholesterol." *See* Final Rule at 1018-19. Moreover, GNC's Healthy Cholesterol Formula does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.

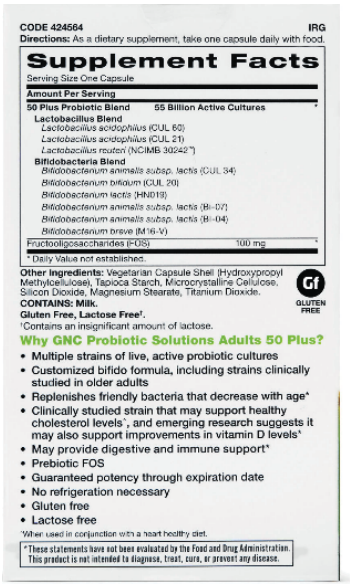
42. As shown above, GNC's Policosanol is labeled, "[m]ay help to maintain normal, healthy cholesterol levels." Exhibit 2. GNC's Policosanol does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.



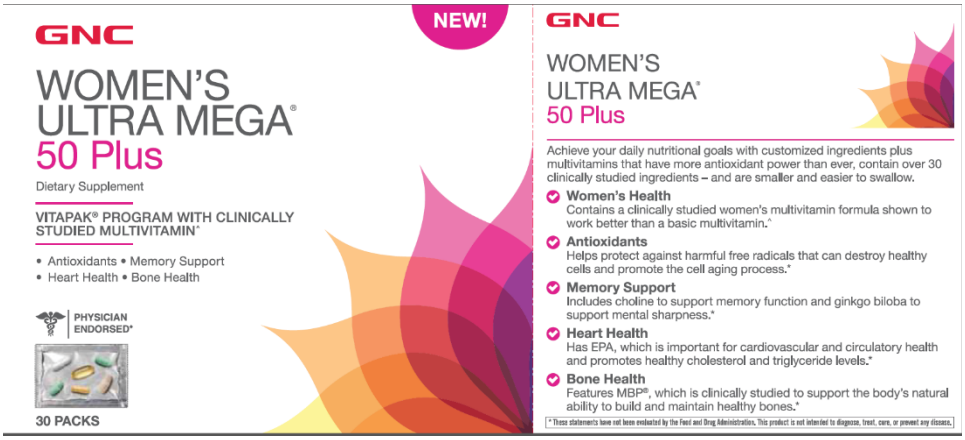


43. As shown above, GNC's Ultra 35 Probiotic Complex with Cholesterol Support is labeled, "[c]linically studied support for healthy cholesterol levels," which is reinforced on the back label which states the product contains "[s]pecialized probiotic strains for cholesterol support." Exhibit 3. GNC's Ultra 35 Probiotic Complex with Cholesterol Support does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.

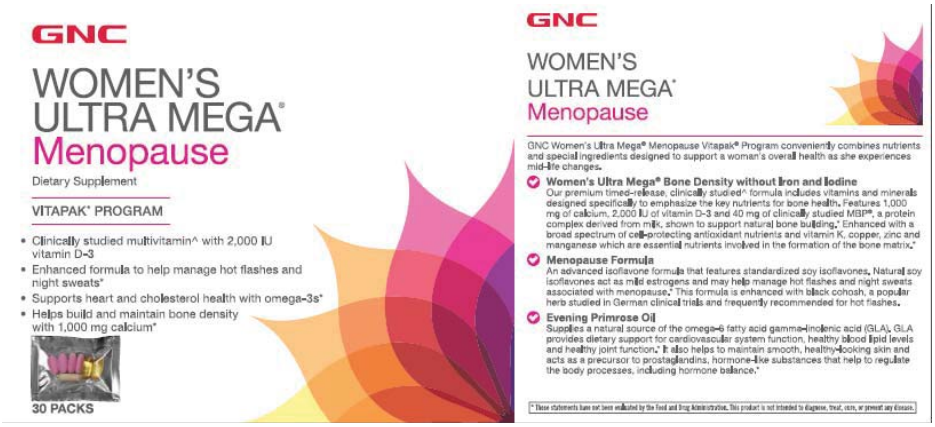




44. As shown above, GNC's Probiotic Solutions Adult 50 Plus is labeled, "[m]ay support healthy cholesterol^ & vitamin D levels." Exhibit 4. The back states it is, "[c]linically studied strain that may support healthy cholesterol levels, and emerging research suggests it may also support improvements in vitamin D levels." Exhibit 4. GNC's Probiotic Solutions Adults 50 Plus does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.



45. As shown above, GNC's Women's Ultra Mega 50 Plus Vitapak product is labeled as "containing over 30 clinically studied ingredients" for, amongst other things, "Heart Health." Exhibit 5. The product is also labeled that it, "[h]as EPA, which is important for cardiovascular and circulatory health and promotes healthy cholesterol and triglyceride levels." Exhibit 5. GNC's Women's Ultra Mega 50 Plus Vitapak does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.



46. As shown above, GNC's Women's Ultra Mega Menopause Vitapak product is labeled as being able to "support a women's overall health," including "heart and cholesterol health with omega-3s." Exhibit 6. GNC's Women's Ultra Mega Menopause Vitapak product does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.

47. The labeling of GNC's Healthy Cholesterol Formula, Policosanol, Ultra 35 Probiotic Complex with Cholesterol Support, Probiotic Solutions Adult 50 Plus, GNC's Women's Ultra Mega 50 Plus Vitapak and Women's Ultra Mega Menopause Vitapak as being able to maintain and/or support normal or healthy cholesterol levels, without also stating that they will only maintain and/or support cholesterol levels for people whose cholesterol levels are already in a normal range, implies that the products will help cure, mitigate, treat or prevent hypercholesterolemia and/or coronary heart disease by helping lower bad cholesterol.

48. GNC's Healthy Cholesterol Formula, Policosanol, Ultra 35 Probiotic Complex with Cholesterol Support, Probiotic Solutions Adult 50 Plus, GNC's Women's Ultra Mega 50 Plus Vitapak or Women's Ultra Mega Menopause Vitapak products have not been approved by FDA to cure, mitigate, treat or prevent hypercholesterolemia or coronary heart disease.

49. FDA has issued warning letters to companies selling dietary supplements claiming to maintain cholesterol levels without explaining that they will only maintain cholesterol when it is already within a normal range because their labeling indicated they are intended for use in the cure, mitigation, treatment, or prevention of disease. *See*, *e.g*, FDA Warning Letter to Nature's Health

Company, LLC dated June 30, 2017[9]; FDA Warning Letter to Orgen Nutraceuticals, Inc. dated October 28, 2015.[10]

50. FDA issues warning letters such as these "only for violations of regulatory significance."[11] FDA warning letters are intended "to correct violations of the statutes or regulations" and "communicate[] the agency's position on a matter." *Id*. at 4-2 to 4-3.

Products Claimed to Cure, Mitigate, Treat or Prevent Osteoporosis

51. Osteoporosis, or porous bone, is a disease characterized by low bone mass and structural deterioration of bone, leading to fragility and increased risk of fractures.[12]

52. Certain risk factors are linked to the development of osteoporosis and contribute to the likelihood of developing the disease, including abnormal absence of menstrual periods and low estrogen levels caused by menopause.[13] While menopause is a normal part of aging and not a disease, one of the changes in a woman's body experiencing menopause is bones become less dense and more vulnerable to fracture.[14] Due to the decrease in bone density, post-menopausal women are more vulnerable to osteoporosis.[15]

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[9] Available online at https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm566680.htm.

[10] Available online at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm471279.htm.

[11] FDA, Regulatory Procedures Manual at p. 4-2 (Mar. 2017), available at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf.

[12] https://www.bones.nih.gov/health-info/bone/osteoporosis/overview.

[13] *Id*.

[14] *See* NIH "What Is Menopause?" available online at https://www.nia.nih.gov/health/what-menopause.

[15] *Id*.

53. Menopause happens when a woman's ovaries stop making estrogen.[16] The average age a woman enters menopause is 51 years, but it can happen sooner naturally and will happen if a woman has her ovaries removed. [17]

54. Estrogen normally acts in the body to help inhibit bone resorption (breakdown).[18] Having low amounts of estrogen being produced by the body, or no estrogen, will cause bone breakdown.[19]

55. There is no cure for osteoporosis, but there are a large number of prescription medications and therapy options depending on the patient's health, comorbid diseases and other medications.[20] Given the serious consequences of osteoporosis, and the complexity of treatment options, osteoporosis is a disease that is not amenable to self-diagnosis or self-treatment.

56. In implementing the regulations governing structure/function claims on dietary supplements, FDA commented on the labeling of dietary supplements with claims about supporting bones and/or bone fragility. Final Rule at 1013, 17-18. FDA concluded that while a claim that a nutrient can help build or maintain strong bones, without more, is a permitted structure function claim, when associated with osteoporosis or another condition the same claim is an unlawful disease claim because it implies treatment for osteoporosis. *Id*. at 1008.

57. Given the association between menopause and osteoporosis, FDA concluded that a claim that a dietary supplement can maintain, build, strengthen or support bone health and/or bone

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[16] *See* "Hormones and Healthy Bones" from the National Osteoporosis Foundation, available online at https://cdn.nof.org/wp-content/uploads/2016/02/Hormones-and-Healthy-Bones-1.pdf at 6.

[17] *Id*. at 6; *See* WebMD "Your Guide to Menopause" available online at https://www.webmd.com/menopause/guide/menopause-information#1 (menopause starts around age 51 and completed within 4 years).

[18] For review, *see* Siddiqui, Jawed A. and Nicola C. Partridge. Physiological Bone Remodeling: Systemic Regulation and Growth Factor Involvement. Physiology (Bethesda). 2016 May;31(3):233-45 available online at https://www.physiology.org/doi/full/10.1152/physiol.00061.2014.

[19] *Id*.

[20] *See, e.g.,* https://www.fda.gov/forconsumers/byaudience/forwomen/ucm118551.htm; https://americanbonehealth.org/fda-approved-treatments/; and Tu., Kristi N. et al. Osteoporosis: A Review of Treatment Options. Pharmacy and Therapeutics. 2018 Feb; 43(2): 92–104.

density combined with an express or implied claim about menopause – including targeting the advertising towards post-menopausal women – expressly or impliedly claims that the product can help cure, mitigate, treat or prevent osteoporosis. *See* Final Rule at 1013 (indicating a statement that a dietary supplement can prevent bone fragility in post-menopausal women is a disease treatment or prevention claim); *id*. at 1014 (indicating the required disclaimer that a claim on a dietary supplement had not been reviewed or approved by FDA was insufficient to make a claim about preventing bone fractures in post-menopausal women due to bone loss into a lawful claim); *id*. at 1017 (claiming that product prevents bone fragility in post-menopausal women clearly implies that the product prevents osteoporosis); *id*. at 1018 (claiming that a dietary supplement will maintain normal bone density in post-menopausal women is a disease claim because post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass). Thus, the labeling of a dietary supplement as being able to maintain, build, strengthen or support bones in menopausal women is an unlawful disease claim.

58. Despite FDA's clear guidance that a dietary supplement cannot be labeled as being able to maintain, build, strengthen or support bone health in menopausal women, GNC's Women's Ultra Mega 50 Plus, Women's Ultra Mega 50 Plus Vitapak and Women's Ultra Mega Menopause Vitapak products explicitly or implicitly claim to cure, mitigate, treat or prevent osteoporosis for menopausal women.

59. GNC's Women's Ultra Mega 50 Plus Vitapak, pictured on Page 15 *supra*, by its very name is targeted towards women 50 years and older who are typically menopausal. Exhibit 5.

60. GNC's Women's Ultra Mega 50 Plus Vitapak is labeled as being a "CLINICALLY STUDIED MULTIVITAMIN" for, among other things, "Bone Health." Exhibit 5. GNC's Women's Ultra Mega 50 Plus Vitapak is also labeled to "[f]eature[] MBP®, which is clinically studied to support the body's natural ability to build and maintain healthy bones." Exhibit 5. As GNC's Women's Ultra Mega 50 Plus Vitapak is targeted towards menopausal women and is labeled to build, support and maintain bones, it is unlawfully labeled to cure, treat, prevent or mitigate osteoporosis.

61. GNC's Women's Ultra Mega Menopause Vitapak, pictured on page 16 *supra*, is by its very name explicitly marketed towards menopausal women. Exhibit 6. The back of the product states it includes a "Menopause formula" with ingredients that "act as mild estrogens...".

62. GNC's Women's Ultra Mega Menopause Vitapak is also labeled as being able to "[h]elp[] build and maintain bone density with 1,000 mg calcium." The back of GNC's Women's Ultra Mega Menopause Vitapak states it contains a combination of "clinically studied ... vitamins and minerals designed specifically to emphasize the key nutrients for bone health." Exhibit 6. GNC's Women's Ultra Mega Menopause Vitapak is also labeled as being "shown to support natural bone building," and as containing ingredients "which are essential nutrients involved in the formation of the bone matrix." Exhibit 6. As GNC's Women's Ultra Mega Menopause Vitapak is marketed for menopausal women and is labeled to build, support and/or maintain bone density, it is unlawfully labeled to cure, treat, prevent or mitigate osteoporosis.

63. GNC's Women's Ultra Mega 50 Plus, pictured above, is by its very name targeted towards women 50 years and older who are typically menopausal. Exhibit 7.

64. GNC's Women's Ultra Mega 50 Plus is labeled as being a "CLINICALLY STUDIED MULTIVITAMIN" for, among other things, "Bone Health." Exhibit 7. GNC's Women's Ultra Mega 50 Plus is also labeled as being able to "Strengthen[] bones with calcium and vitamin D-3," and as containing "a potent calcium and vitamin D complex to support strong bones." Exhibit 7. As GNC's

Women's Ultra Mega 50 Plus is targeted towards menopausal women and is labeled to strengthen and support bones, it is unlawfully labeled to cure, treat, prevent or mitigate osteoporosis.

65. The labeling of GNC's Women's Ultra Mega 50 Plus Vitapak, Women's Ultra Mega Menopause Vitapak, and Women's Ultra Mega 50 Plus as being able to build, support, and/or maintain bones implies that the products will help cure, mitigate, treat or prevent osteoporosis because the products are targeted towards menopausal women who typically experience osteoporosis.

66. None of GNC's Women's Ultra Mega 50 Plus, Women's Ultra Mega Menopause Vitapak or Women's Ultra Mega 50 Plus Vitapak products have been approved by FDA for the treatment, prevention, cure or mitigation of osteoporosis.

Labeling Products with Drug or Disease Claims without FDA Approval is Misleading

67. The labeling of products that claim to cure, treat, prevent or mitigate diseases or other health related conditions, when they have not been approved as being safe and effective to do so, is misleading. *See* FDA Health Fraud Scams[21].

68. To the extent GNC's supplements cannot cure, treat, prevent or mitigate the diseases or conditions for which they imply treatment, the labeling of the supplements is false and misleading.

69. Even if GNC's supplements are not completely ineffective for the advertised benefits, the labeling of GNC's products as dietary supplements, and not as over-the-counter ("OTC") or prescription drugs, is still misleading as the labeling omits information that is material to consumers.

70. Congress charged FDA with ensuring that all drugs (*i.e.*, prescription and OTC) are not only safe and effective, but that their labeling adequately informs users of the risks and benefits of the product, and that its labeling is truthful and not misleading.

71. FDA makes its determination on all drug approval (*i.e.*, prescription and OTC) based on a comprehensive scientific evaluation of a product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling. 21 U.S.C. § 355(d).

72. FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the

[21] Available online at https://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/default.htm.

product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance. 71 Fed. Reg. 3922, 3934 (January 24, 2006).

Prescription Drug Labeling

73. For prescription drugs, the centerpiece of risk management generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate. 71 Fed. Reg. at 3934

74. Labeling, as defined by the FDCA, "means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

75. The requirements for prescription drug labeling are set forth in 21 C.F.R. § 201.56. Amongst other things, prescription drug labeling must include:

a. A summary of the essential scientific information needed for the safe and effective use of the drug;

b. the informative must be informative and accurate

c. the information may not be promotional in tone, and nothing false or misleading may be included;

d. no implied claims or suggestions for use if evidence of safety or efficacy is lacking; and

e. based, whenever possible, on human testing.

76. The FDA approves prescription drug labels based on its analysis of a new drug application or biologics license application, and contains information "necessary for safe and effective use." 71 Fed. Reg 3911-01, 3922 (January 24, 2006).

77. The primary purpose of prescription drug labeling is to give healthcare practitioners the information they need to prescribe drugs appropriately. *Id*. at 3961. The information in prescription drug labeling, and the format it is presented, is to give healthcare professionals the ability to access, read and use drug information. *Id*. at 3923.

78. Amongst other things, prescription drug labeling must include: Highlights of prescribing information that includes the dosage; concise summary of any boxed warnings; indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; and adverse reactions. 21 C.F.R. § 201.57(a).

79. Prescription drug labeling must also include Full Prescribing information with appropriate headings and subheadings that detail any boxed warnings; indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; adverse reactions; drug interactions; use in specific populations, pregnancy risks; effects on reproductive potential; pediatric use; geriatric use; description including chemical and physical information; clinical pharmacology; nonclinical toxicology; clinical studies; references; proper storage and handling; patient counseling information. 21 C.F.R. § 201.57(b)-(c).

80. The information must be presented in a uniform way, with a specific format and with minimal type size requirements to make reading and understanding the information easy. 21 C.F.R. § 201.57(d).

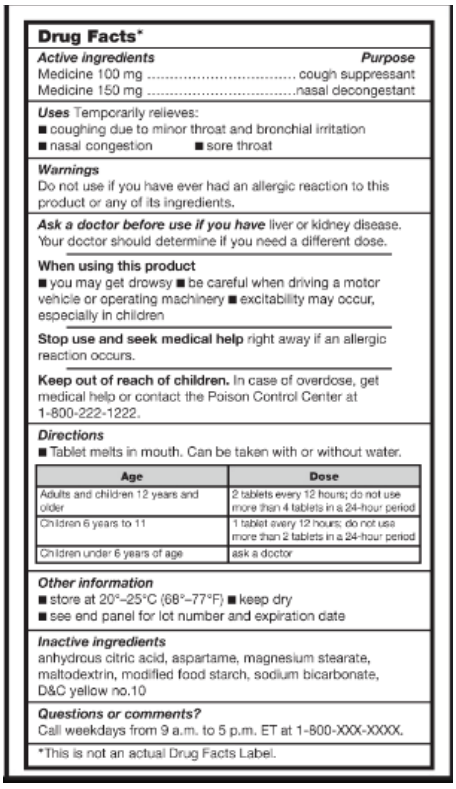
81. The ultimate purpose of prescription drug labeling is to give healthcare practitioners the information they need, in a uniform and easily-readable format, to keep consumers from harm through the use of appropriate drugs. Consumers rely on their health care practitioners to have all of the critical information about a drug when recommending it for a specific purpose. Thus, the failure to label prescription drugs accurately, with all of the required information and in the required format, is material to consumers and it can lead to harm through the misuse of such drugs.

OTC Drug Labeling

82. Even if GNC's Products implied treatment for conditions amenable to self-diagnosis and treatment, allowing them to be classified as OTC drugs, the labeling omits information that is material to consumers. Indeed, proper labeling of OTC drugs may be more material to consumers than prescription drug labeling because there is no professional intermediary, such as a doctor or pharmacist, between the drug and the consumer.

83. As stated by FDA, reading the label of an OTC drug is the most important part of taking care of yourself or your family when using OTC medications, especially because many OTC medicines are taken without seeing a doctor.[22] The label should tell a consumer what a medicine is supposed to do, who should or should not take it, and how to use it.

84. Amongst other things, all OTC drug labels must include "Drug Facts" with a specific graphical design to be a visual cue to consumers for introducing required information as shown below (21 C.F.R. § 201.66(c)(1)):



Drug Facts*

Active ingredients ***Purpose***
Medicine 100 mg ..... cough suppressant
Medicine 150 mg .....nasal decongestant

Uses Temporarily relieves:
■ coughing due to minor throat and bronchial irritation
■ nasal congestion ■ sore throat

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product
■ you may get drowsy ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children

Stop use and seek medical help right away if an allergic reaction occurs.

Keep out of reach of children. In case of overdose, get medical help or contact the Poison Control Center at 1-800-222-1222.

Directions
■ Tablet melts in mouth. Can be taken with or without water.

Age	Dose
Adults and children 12 years and older	2 tablets every 12 hours; do not use more than 4 tablets in a 24-hour period
Children 6 years to 11	1 tablet every 12 hours; do not use more than 2 tablets in a 24-hour period
Children under 6 years of age	ask a doctor

Other information
■ store at 20°–25°C (68°–77°F) ■ keep dry
■ see end panel for lot number and expiration date

Inactive ingredients
anhydrous citric acid, aspartame, magnesium stearate, maltodextrin, modified food starch, sodium bicarbonate, D&C yellow no.10

Questions or comments?
Call weekdays from 9 a.m. to 5 p.m. ET at 1-800-XXX-XXXX.

*This is not an actual Drug Facts Label.

[22] FDA The Over-the-Counter Medicine Label: Take a Look available online at https://www.fda.gov/drugs/emergencypreparedness/bioterrorismanddrugpreparedness/ucm133411.htm.

85. "Active Ingredients" must have an established name, and list the quantity or proportion of each active ingredient immediately below a prominent title to enable consumers to quickly and systematically compare ingredient within products for similar uses. 64 Fed. Reg. 13254-01, 13260.

86. "Purpose" is the FDA-approved description of the principal intended action of the drug or each active ingredient. 21 C.F.R. § 201.66(c)(3).

87. "Uses" provides the indications for use of the product. 21 C.F.R. § 201.66(c)(4).

88. "Warnings" provides specific information and subheadings including whether the product is for external use only and, as appropriate, for rectal or vaginal use; Reye's syndrome warning if the product contains salicylates; allergic reaction and asthma alert warnings; contraindications when consumers should not use the product unless a doctor directs the usage; preexisting conditions warnings; juvenile warnings; pregnancy warnings; accidental ingestion/overdose warning. 21 C.F.R. § 201.66(c)(5).

89. Directions for use, such as specific age categories, how much to take, how to take, and how often and how long to take. 21 C.F.R. § 201.66(c)(6).

90. Other Information required by the FDA specifically excluding any promotional material as it is generally not necessary for the safe and effective use of the product. 21 C.F.R. § 201.66(c)(7) and 64 Fed. Reg. 13254-01, 13263.

91. Inactive Ingredients are to be listed in accordance with 21 C.F.R. § 201.66(c)(8).

92. Questions or Comments that provides a telephone number for a source to answer questions about the product. 21 C.F.R. § 201.66(c)(9).

93. Having all of the required information, and have it presented in a uniform way, is material to consumers who wish to make an educated decision about what drugs they are putting into their bodies, as well as whether it is the best and/or most economical product for what they are trying to accomplish. The failure to include any of this information on an OTC drug product is not only unlawful, but it prevents consumers from being able to comparative shop for the most appropriate product for their needs.

94. Unless FDA has given a specific exemption from including required information on an OTC drug's label, its inclusion is material to consumers. The omission of any information from the

labeling of a food or drug that is material in light of the claims made for the product or the consequences that may result from using the product deems the product misleading and misbranded. 21 C.F.R. § 1.21(a).

GNC Refused To Cease Its Wrongdoing

95. On November 17, 2017, Mr. Clark and Ms. Labajo, through their counsel and pursuant to California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1782, sent GNC a certified letter notifying GNC of particular violations of Civil Code § 1770, and demanded that GNC correct, repair or otherwise rectify the problems associated with its unlawful behavior which are in violation of Civil Code § 1770 ("CLRA Letter"). A copy of the CLRA Letter is attached hereto as Exhibit 9 (exhibits thereto omitted).[23]

96. GNC failed to respond to the CLRA Letter.

97. To date, the labels of the Products being the unlawful claims detailed herein have not changed, and GNC has yet to respond to the CLRA Letter.

98. As GNC has failed to respond to the CLRA Letter, and the Products' labels have not changed, it appears GNC is and continues to be unwilling to change the labeling of the Products to remove the drug claims identified in the CLRA Letter and throughout this Complaint, or to submit a new drug application with FDA in order to have its products approved as new drugs with appropriate drug labeling.

99. GNC has not stopped using or corrected, repaired or otherwise rectified the unlawful labeling practices identified in the CLRA Letter and described in this Complaint.

FIRST CAUSE OF ACTION
("Unlawful" Business Practices in Violation of
The Unfair Competition Law, Bus. & Prof. Code §§ 17200, *et seq.*)

100. Plaintiffs hereby incorporate all other paragraphs of this Complaint and restate them as if fully set forth herein.

[23] The CLRA Letter also set forth claims regarding abnormal blood glucose levels, inflammation, oxidative stress, and statin therapy in other of GNC's products. However, Plaintiffs are not asserting any claims regarding abnormal blood glucose levels, inflammation, oxidative stress, and statin therapy in GNC's products in this First Amended Complaint.

101. California's Unfair Competition Law ("UCL") defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice. Cal. Bus. & Prof. Code § 17200.

102. A business practice is "unlawful" if it violates any established state or federal law.

103. Sherman Law § 111550 prohibits the sale, delivery or gift of any new drug without approval of a new drug application by FDA or California's Department of Health Services.

104. Sherman Law § 109925 and FDCA § 201(g)(1) define "drug" as, amongst other things, any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals. Any food for which a health claim has been approved by FDA pursuant to FDCA §§ 403(r)(1)(B) and 403(r)(3) for conventional foods, or §§ 403(r)(1)(B) and 403(r)(5)(D) for dietary supplements, is not a drug solely because the label or labeling contains such a claim. Unlike conventional foods, dietary supplements cannot be labeled with health claims based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government with responsibility for public health protection or nutrition research.

105. A "new drug" is any drug which has not been proven to be safe and effective for use under conditions prescribed, recommended or suggested in the labeling or advertising thereof. 21 C.F.R. § 321(p); Sherman Law 10998.

106. As explained above, GNC's Products are new drugs as they are labeled as being intended to cure, treat, mitigate or prevent hypercholesterolemia, coronary heart disease and/or osteoporosis in humans. However, none of GNC's Products identified in this complaint have been approved as a new drug by FDA or California's Department of Health Services for these purposes.

107. GNC violated and continues to violate Sherman Law § 111550 through the sale, delivery or gift of each of the new drug products identified herein without approval of a new drug application by FDA or California's Department of Health Services, and hence also violated and continues to violate the "unlawful" prong of the UCL.

108. The Sherman Law also prohibits the advertisement of any food or drug that is misbranded. Sherman Law § 110398. Advertisement for the purpose of the Sherman Law includes any representations about a product including statements on the packaging. Sherman Law § 109885.

109. Sherman Law § 111440 prohibits the manufacture, sale, delivery, holding or offer to sell a misbranded drug, and § 111445 prohibits the misbranding a drug.

110. Food and drugs are misbranded if their labeling is false or misleading in any particular. Sherman Law §§ 110660 and 111330 (respectively).

111. The labeling of a food or drug is misleading if it fails to reveal facts that are material in light of other representations made, or if it fails to include affirmative disclosure of material facts required by FDA regulations promulgated pursuant to the FDCA. 21 C.F.R. § 1.21.

112. The Sherman Law adopts FDA regulations of food and drugs as the law of California. Sherman Law §§ 110100 (food); 110110 (new drugs) 110111 (OTC drugs).

113. GNC's Products labeled as drugs fail to provide material information required by FDA for all drug products as explained above. Due to GNC's omission of this material information, the Products are misbranded and GNC violated, and continues to violate, 21 C.F.R. § 1.21 and Sherman Law §§ 110110 and 110111.

114. Moreover, due to the omission of the material drug information which renders the Products misbranded, GNC violated, and continues to violate, Sherman Law §§ 111440, 111445, 110660, 111330 by misbranding the Products, manufacturing, selling, delivering and offering to sell misbranded Products.

115. GNC's identical conduct that violates the Sherman Law also violates the FDCA, 21 U.S.C. §§ 331(a), (b), (d), (g), 352 and 355, and FDA regulations, 21 C.F.R. § 201.57, 21 C.F.R. § 201.66. This identical conduct serves as the sole factual basis of each cause of action brought by this Complaint, and Plaintiffs do not seek to enforce any of the state law claims raised herein to impose any standard of conduct that exceeds that which would violate the FDCA and applicable FDA regulations.

116. By committing the unlawful acts and practices alleged above, GNC has engaged, and continues to be engaged, in unlawful business practices within the meaning of the UCL.

117. As a result of GNC's unlawful conduct, GNC has obtained money from Plaintiffs, and Plaintiffs have suffered injury in fact and lost money or property. As such, Plaintiffs request that this

Court enjoin GNC from continuing to violate the UCL or violating it in the same fashion in the future as discussed herein pursuant to Cal. Bus. & Prof. Code §17203.

JURY DEMAND

Plaintiffs demand a jury trial on all causes of action and/or issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for relief and judgment against GNC as follows:

A. A declaration and Order enjoining GNC from misbranding, manufacturing, selling, delivering, holding or offering for sale, selling or offering for sale, delivering or proffering for delivery the Products labeled with unapproved drug or disease claims in violation of California's Sherman Law and other applicable laws and regulations as specified in this Complaint;

B. An Order awarding Plaintiffs their costs of suit, attorneys' fees and pre-and post-judgment interest; and

C. Such other and further relief as the Court may deem just and proper.

Dated: November 26, 2019

FEINSTEIN DOYLE PAYNE & KRAVEC, LLC

By: */s Wyatt A. Lison*
Wyatt A. Lison

429 Fourth Avenue, Suite 1300
Pittsburgh, PA 15219
Telephone: (412) 281-8400
Facsimile: (412) 281-1007

John Peter Zavez (admitted *pro hac vice*)
ADKINS, KELSTON & ZAVEZ, P.C.
90 Canal Street, Suite 120
Boston, MA 02114
Telephone: (617) 367-1040
Facsimile: (617) 742-8280

J. Benjamin Blakeman (SBN - 60596)
BLAKEMAN LAW
8383 Wilshire Boulevard, Suite 510
Beverly Hills, CA 90211
Telephone: (213) 629-9922
Email: ben@lifeinsurance-law.com

ATTORNEYS FOR PLAINTIFFS

EXHIBIT 1

Lutemax® 2020 is a trademark of OmniActive Health Technologies.

CardioAid® and the CardioAid® logo are registered trademarks of Archer Daniels Midland Company.

KEEP OUT OF REACH OF CHILDREN.

Store in a cool, dry place.

^Foods containing at least 0.5 g per serving of phytosterols eaten with meals or snacks for a daily total intake of 2 g as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. Preventive Nutrition® Healthy Cholesterol Formula supplies 1.2 g of phytosterols.

*** This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

For More Information:
1-888-462-2548

SHOP NOW @ GNC.COM

Distributed by:
General Nutrition Corporation
Pittsburgh, PA 15222 USA

0 48107 11840 2

GNC
PREVENTIVE NUTRITION®

Healthy Cholesterol FORMULA

SCIENTIFICALLY FORMULATED NUTRITION SOLUTIONS

- Supports normal, healthy cholesterol & triglyceride levels with clinically studied black tea extract*
- Features potent phytosterols, which may reduce the risk of heart disease^

SCIENTIFICALLY FORMULATED

DIETARY SUPPLEMENT
90 CAPLETS

CODE 714412 GRG

Directions: As a dietary supplement, take one caplet three times daily with food on separate occasions.

Supplement Facts

Serving Size Three Caplets
Servings Per Container 30

Amount Per Serving		% Daily Value
Calcium (as Dicalcium Phosphate)	50 mg	5%
Cholesterol Support Blend		
CardioAid® Phytosterols	1200 mg	*
Black Tea Leaf Extract (*Camellia sinensis*)	1000 mg	*
Antioxidant Support Complex		
Coenzyme Q-10	100 mg	*
Betaine (as Betaine Hydrochloride)	100 mg	*
Lutemax® 2020 Lutein	1000 mcg	*
Zeaxanthin	200 mcg	*
Inflammatory Response Support Blend		
Cutch Tree Wood & Bark Extract (*Acacia catechu*), Chinese Skullcap Root Extract (*Scutellaria baicalensis*)	62.5 mg	*

* Daily Value not established.

Other Ingredients: Dicalcium Phosphate, Cellulose.

This product contains 20 mg of naturally occurring caffeine per caplet from clinically studied Black Tea Extract.

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.

Conforms to USP <2091> for weight.

No Sugar, No Artificial Colors, No Artificial Flavors, No Preservatives, Sodium Free, No Wheat, Gluten Free, No Dairy, Yeast Free.

Gf GLUTEN FREE

Lot No./Best By:


GNC
PREVENTIVE NUTRITION®
Healthy Cholesterol
FORMULA
PHYSICIAN FORMULATED NUTRITION SOLUTIONS
Supports normal, healthy cholesterol & triglyceride levels with clinically studied black tea extract*
Features potent phytosterols, which may reduce the risk of heart disease^
PHYSICIAN ENDORSED
DIETARY SUPPLEMENT
90 CAPLETS


CODE 714412
AOG
Directions: As a dietary supplement, take one caplet three times daily with food on separate occasions.
Supplement Facts
Serving Size Three Caplets
Servings Per Container 30
Amount Per Serving
% Daily Value
Calcium (as Dicalcium Phosphate) 50 mg 5%
Cholesterol Support Blend
CardioAid™ Phytosterols 1200 mg *
Black Tea Leaf Extract (Camellia sinensis) 1000 mg *
Antioxidant Support Complex
Coenzyme Q-10 100 mg *
Betaine (as Betaine Hydrochloride) 100 mg *
Lutemax 2020™ Lutein 1000 mcg *
Zeaxanthin 200 mcg *
Inflammatory Response Support Blend
Cutch Tree Wood & Bark Extract (Acacia catechu), Chinese Skullcap Root Extract (Scutellaria baicalensis) 62.5 mg *
* Daily Value not established.
Other Ingredients: Dicalcium Phosphate, Cellulose.
This product contains 20 mg of naturally occurring caffeine per caplet from clinically studied Black Tea Extract.
WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.
Conforms to USP <2091> for weight.
No Sugar, No Artificial Colors, No Artificial Flavors, No Preservatives, Sodium Free, No Wheat, No Gluten, No Dairy, Yeast Free.

EXHIBIT 2

KEEP OUT OF REACH OF CHILDREN.
Store in a cool, dry place.

For More Information:
1-888-462-2548

SHOP NOW @ GNC.COM

Distributed by:
General Nutrition Corporation
Pittsburgh, PA 15222

GNC

Policosanol

10 MG

May help to maintain normal, healthy cholesterol levels*

DIETARY SUPPLEMENT
60 TABLETS

CODE 061822 **BRG**

Directions: As a dietary supplement, take one tablet daily. For maximum support, take as directed every day.

Supplement Facts

Serving Size One Tablet

Amount Per Serving	
Policosanol	10 mg*

* Daily Value not established.

Other Ingredients: Dicalcium Phosphate, Cellulose.

Conforms to USP <2091> for weight.
Meets USP <2040> disintegration.

No Sugar, No Artificial Colors, No Artificial Flavors, No Preservatives, Sodium Free, No Wheat, Gluten Free, No Corn, No Soy, No Dairy, Yeast Free.

*** This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Lot No./Best By:


GNC
Policosanol
10 MG
May help to maintain normal, healthy cholesterol levels*
DIETARY SUPPLEMENT
60 TABLETS

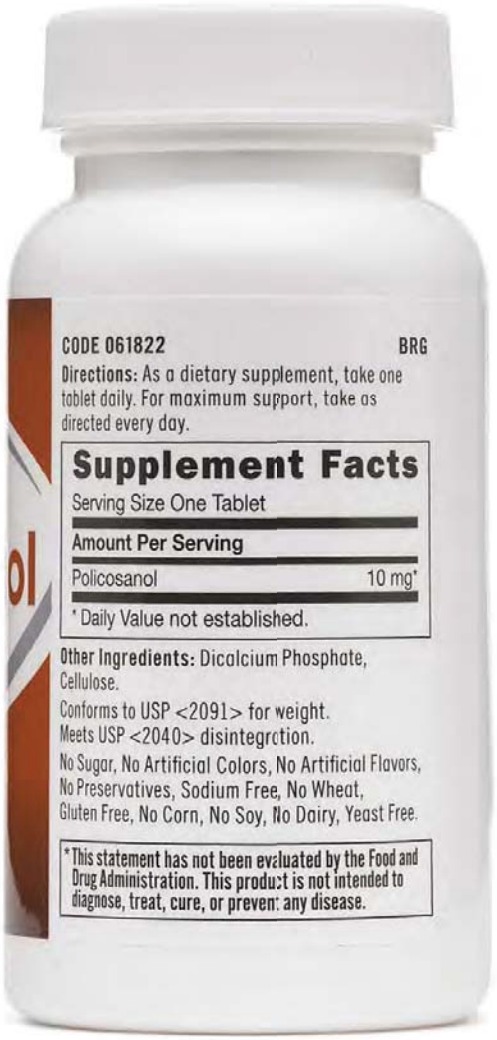

CODE 061822
BRG
Directions: As a dietary supplement, take one tablet daily. For maximum support, take as directed every day.
Supplement Facts
Serving Size One Tablet
Amount Per Serving
Policosanol 10 mg*
* Daily Value not established.
Other Ingredients: Dicalcium Phosphate, Cellulose.
Conforms to USP <2091> for weight.
Meets USP <2040> disintegration.
No Sugar, No Artificial Colors, No Artificial Flavors, No Preservatives, Sodium Free, No Wheat, Gluten Free, No Corn, No Soy, No Dairy, Yeast Free.
* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

EXHIBIT 3

CODE 424553 GRG

Directions: As a dietary supplement, take two capsules daily with food. For maximum results, take one capsule on two separate occasions and follow a heart-healthy lifestyle (see GNC.com for plan).

Supplement Facts

Serving Size Two Capsules
Servings Per Container 30

Amount Per Serving		
LAB4 Probiotics	25 Billion CFU	*
Lactobacillus acidophilus (CUL 60)		
Lactobacillus acidophilus (CUL 21)		
Bifidobacterium bifidum (CUL 20)		
Bifidobacterium animalis subsp. lactis (CUL 34)		
Cholesterol Support Probiotics	10 Billion CFU	*
Lactobacillus plantarum (CUL 66)		
Lactobacillus reuteri NCIMB 30242™		
Fructooligosaccharides (FOS)	200 mg	*

* Daily Value not established.

Other Ingredients: Vegetarian Capsule Shell (Hydroxypropyl Methylcellulose), Silicon Dioxide, Microcrystalline Cellulose, Magnesium Stearate, Titanium Dioxide.

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.

Gluten Free, Lactose Free.

GLUTEN FREE

Why GNC Ultra Probiotic with Cholesterol Support?

- Multiple strains of live, active probiotic cultures
- Specialized probiotic strains for cholesterol support*
- Prebiotic fiber to nourish intestinal flora
- Guaranteed potency through expiration date
- No refrigeration necessary
- Gluten free
- Lactose free

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

GNC

ULTRA 35 BILLION CFUs PROBIOTIC COMPLEX WITH CHOLESTEROL SUPPORT

DIETARY SUPPLEMENT

- **Probiotic with 35 billion active cultures and 6 strains.**
- **Clinically studied support for healthy cholesterol levels.***
- **Replenishes beneficial bacteria important for optimal digestive and immune health.***
- **No refrigeration required.**

60 VEGETARIAN CAPSULES

GUARANTEED POTENCY 35

NCIMB 30242™ is a trademark of UAS Laboratories, LLC and is used under license and with permission.

ACTUAL SIZE

KEEP OUT OF REACH OF CHILDREN.
Store in a cool, dry place.
No refrigeration required.

For More Information:
1-888-462-2548
SHOP NOW @ GNC COM

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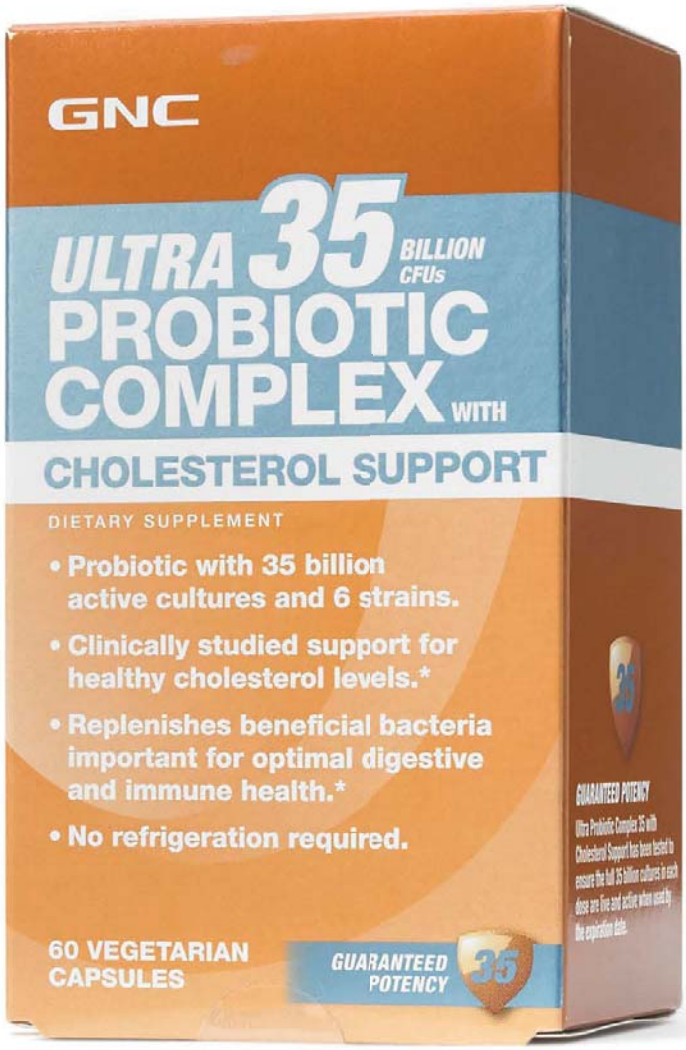
General Nutrition Corporation
Pittsburgh, PA 15222 USA
Made in the UK

Please recycle this box.

35

GUARANTEED POTENCY

Ultra Probiotic Complex 35 with Cholesterol Support has been tested to ensure the full 35 billion cultures in each dose are live and active when used by the expiration date.


GNC
ULTRA 35 BILLION CFUs
PROBIOTIC COMPLEX WITH
CHOLESTEROL SUPPORT
DIETARY SUPPLEMENT
• Probiotic with 35 billion active cultures and 6 strains.
• Clinically studied support for healthy cholesterol levels.*
• Replenishes beneficial bacteria important for optimal digestive and immune health.*
• No refrigeration required.
60 VEGETARIAN CAPSULES
GUARANTEED POTENCY
35
GUARANTEED POTENCY

CODE 424553 GRG

Directions: As a dietary supplement, take two capsules daily with food. For maximum results, take one capsule on two separate occasions and follow a heart-healthy lifestyle (see GNC.com for plan).

Supplement Facts

Serving Size Two Capsules
Servings Per Container 30

Amount Per Serving		
LAB4 Probiotics	25 Billion CFU	*
Lactobacillus acidophilus (CUL 60)		
Lactobacillus acidophilus (CUL 21)		
Bifidobacterium bifidum (CUL 20)		
Bifidobacterium animalis subsp. lactis (CUL 34)		
Cholesterol Support Probiotics	10 Billion CFU	*
Lactobacillus plantarum (CUL 66)		
Lactobacillus reuteri NCIMB 30242™		
Fructooligosaccharides (FOS)	200 mg	*

* Daily Value not established.

Other Ingredients: Vegetarian Capsule Shell (Hydroxypropyl Methylcellulose), Silicon Dioxide, Microcrystalline Cellulose, Magnesium Stearate, Titanium Dioxide.

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.

Gluten Free, Lactose Free.

GF GLUTEN FREE

Why GNC Ultra Probiotic with Cholesterol Support?

- Multiple strains of live, active probiotic cultures
- Specialized probiotic strains for cholesterol support*
- Prebiotic fiber to nourish intestinal flora
- Guaranteed potency through expiration date
- No refrigeration necessary
- Gluten free
- Lactose free

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

EXHIBIT 4

CODE 424564 IRG

Directions: As a dietary supplement, take one capsule daily with food.

Supplement Facts

Serving Size One Capsule

Amount Per Serving		
50 Plus Probiotic Blend	**55 Billion Active Cultures**	*
Lactobacillus Blend		
Lactobacillus acidophilus (CUL 60)		
Lactobacillus acidophilus (CUL 21)		
Lactobacillus reuteri (NCIMB 30242™)		
Bifidobacteria Blend		
Bifidobacterium animalis subsp. lactis (CUL 34)		
Bifidobacterium bifidum (CUL 20)		
Bifidobacterium lactis (HN019)		
Bifidobacterium animalis subsp. lactis (Bi-07)		
Bifidobacterium animalis subsp. lactis (BI-04)		
Bifidobacterium breve (M16-V)		
Fructooligosaccharides (FOS)	100 mg	*

* Daily Value not established.

Other Ingredients: Vegetarian Capsule Shell (Hydroxypropyl Methylcellulose), Tapioca Starch, Microcrystalline Cellulose, Silicon Dioxide, Magnesium Stearate, Titanium Dioxide.

CONTAINS: Milk.

Gluten Free, Lactose Free†.

†Contains an insignificant amount of lactose.

GLUTEN FREE

Why GNC Probiotic Solutions Adults 50 Plus?

- Multiple strains of live, active probiotic cultures
- Customized bifido formula, including strains clinically studied in older adults
- Replenishes friendly bacteria that decrease with age*
- Clinically studied strain that may support healthy cholesterol levels^, and emerging research suggests it may also support improvements in vitamin D levels*
- May provide digestive and immune support*
- Prebiotic FOS
- Guaranteed potency through expiration date
- No refrigeration necessary
- Gluten free
- Lactose free

^When used in conjunction with a heart healthy diet.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

GNC GNC

Probiotic SOLUTIONS

Probiotic SOLUTIONS

ACTUAL SIZE

ADULTS 50 PLUS

POTENCY GUARANTEED

55 BILLION CFUs

- Customized multi-strain bifido formula, including strains clinically studied in adults 50 & over
- May support healthy cholesterol^ & vitamin D levels*

NCIMB 30242™ is a trademark of UAS Laboratories, LLC and is used under license and with permission.

KEEP OUT OF REACH OF CHILDREN.

Store in a cool, dry place.

No refrigeration required.

Guaranteed Potency

Probiotic Solutions Adults 50 Plus has been tested to ensure the full 55 billion cultures in each dose are live and active when used by the expiration date.

GUARANTEED POTENCY

For More Information:
1-888-462-2548
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Distributed by:
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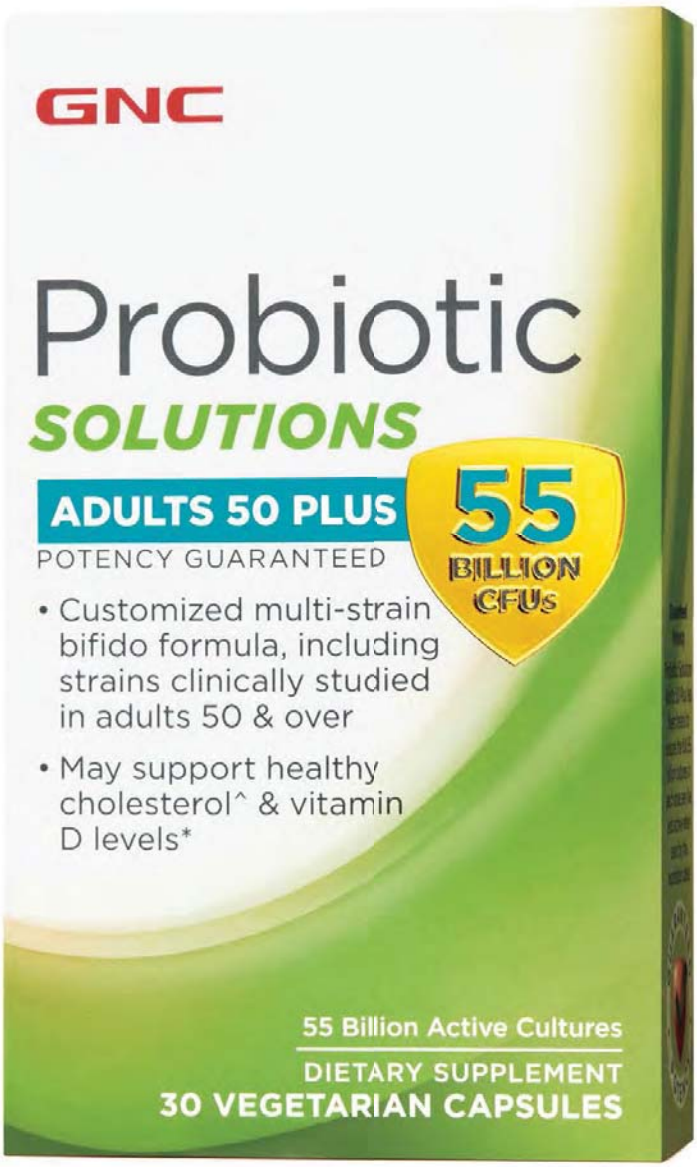
Pittsburgh, PA 15222 USA
Made in the UK

55 Billion Active Cultures

DIETARY SUPPLEMENT

30 VEGETARIAN CAPSULES


GNC
Probiotic
SOLUTIONS
ADULTS 50 PLUS
POTENCY GUARANTEED
55
BILLION
CFUs
• Customized multi-strain bifido formula, including strains clinically studied in adults 50 & over
• May support healthy cholesterol^ & vitamin D levels*
55 Billion Active Cultures
DIETARY SUPPLEMENT
30 VEGETARIAN CAPSULES

CODE 424564 **IRG**

Directions: As a dietary supplement, take one capsule daily with food.

Supplement Facts

Serving Size One Capsule

Amount Per Serving		
50 Plus Probiotic Blend	**55 Billion Active Cultures**	*
Lactobacillus Blend		
Lactobacillus acidophilus (CUL 60)		
Lactobacillus acidophilus (CUL 21)		
Lactobacillus reuteri (NCIMB 30242™)		
Bifidobacteria Blend		
Bifidobacterium animalis subsp. lactis (CUL 34)		
Bifidobacterium bifidum (CUL 20)		
Bifidobacterium lactis (HN019)		
Bifidobacterium animalis subsp. lactis (Bi-07)		
Bifidobacterium animalis subsp. lactis (BI-04)		
Bifidobacterium breve (M16-V)		
Fructooligosaccharides (FOS)	100 mg	*

* Daily Value not established.

Other Ingredients: Vegetarian Capsule Shell (Hydroxypropyl Methylcellulose), Tapioca Starch, Microcrystalline Cellulose, Silicon Dioxide, Magnesium Stearate, Titanium Dioxide.

CONTAINS: Milk.

Gluten Free, Lactose Free†.

GF GLUTEN FREE

†Contains an insignificant amount of lactose.

Why GNC Probiotic Solutions Adults 50 Plus?

- Multiple strains of live, active probiotic cultures
- Customized bifido formula, including strains clinically studied in older adults
- Replenishes friendly bacteria that decrease with age*
- Clinically studied strain that may support healthy cholesterol levels^, and emerging research suggests it may also support improvements in vitamin D levels*
- May provide digestive and immune support*
- Prebiotic FOS
- Guaranteed potency through expiration date
- No refrigeration necessary
- Gluten free
- Lactose free

^When used in conjunction with a heart healthy diet.

*** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

EXHIBIT 5

CODE 208412 BQG

Directions: As a dietary supplement, take the contents of one pack daily with food.

Each pack contains:

Women's Ultra Mega® 50 Plus Multivitamin

Supplement Facts

Serving Size Two Light Green Caplets

Amount Per Serving		% Daily Value
Vitamin A (as 50% beta-Carotene & 50% Retinyl Acetate)	5000 IU	100%
Vitamin C (as Ascorbic Acid & Calcium Ascorbate)	300 mg	333%
Vitamin D (as Cholecalciferol D-3)	1600 IU	400%
Vitamin E (as Natural d-alpha Tocopheryl Acetate)	30 IU	100%
Vitamin K (as Phytonadione)	80 mcg	100%
Thiamin (Vitamin B-1)(as Thiamin Mononitrate)	50 mg	3333%
Riboflavin (Vitamin B-2)	50 mg	3941%
Niacin (as Niacinamide & Niacin)	50 mg	250%
Vitamin B-6 (as Pyridoxine Hydrochloride)	50 mg	2500%
Folic Acid	400 mcg	100%
Vitamin B-12 (as Cyanocobalamin)	50 mcg	833%
Biotin	300 mcg	100%
Pantothenic Acid (as Calcium d-Pantothenate)	50 mg	500%
Calcium (as Calcium Carbonate & Calcium Ascorbate)	500 mg	50%
Iodine (as Potassium Iodide)	150 mcg	100%
Magnesium (as Magnesium Oxide)	50 mg	13%
Zinc (as Zinc Oxide)	15 mg	100%
Selenium (as L-Selenomethionine)	200 mcg	286%
Copper (as Copper Sulfate)	2 mg	100%
Manganese (as Manganese Sulfate)	2 mg	100%
Chromium (as Chromium Chloride)	120 mcg	100%
Molybdenum (as Sodium Molybdate)	75 mcg	100%
Super Antioxidant Blend		
alpha-Lipoic Acid	25 mg	†
Lutemax® 2020 Lutein	2 mg	†
Lycopene	1 mg	†
Turmeric Root Extract (*CurcuWIN™)(Curcuma longa*, Standardized to Curcuminoids)	500 mg	†
Zeaxanthin (as Zeaxanthin Isomers)	400 mcg	†
Astaxanthin (from *Haematococcus pluvialis*)	50 mcg	†
beta-Cryptoxanthin	10 mcg	†
Brain & Circulatory Support		
Choline (as Choline Bitartrate)	10 mg	†
Inositol	10 mg	†
Ginkgo biloba Leaf Powder	5 mg	†
Bacopa monnieri Leaf Extract	4 mg	†
Boron (as Sodium Borate)	2 mg	†
Phosphatidyl Serine	1 mg	†
Vanadium (as Sodium Metavanadate)	10 mcg	†
Eye & Skin Health Complex		
Silica (as Silicon Dioxide)	4 mg	†
Black Currant Fruit Extract (*Ribes nigrum*)	2.5 mg	†
Blueberry Fruit Powder (*Vaccinium angustifolium*)	2.5 mg	†
Cranberry Fruit Concentrate (*Vaccinium macrocarpon*)	2.5 mg	†
Bilberry Fruit Powder (*Vaccinium myrtillus*)	2.5 mg	†
Elderberry Fruit Powder (*Sambucus nigra*)	2.5 mg	†
Hyaluronic Acid (as Sodium Hyaluronate)	2 mg	†
Resveratrol	1 mg	†
Grape Seed Extract (*Vitis vinifera*)(Standardized to Polyphenols)	1 mg	†

† Daily Value not established.

Other Ingredients: Cellulose, Stearic Acid Vegetable Source, Magnesium Stearate Vegetable Source, Titanium Dioxide (Natural Mineral Whitener), Natural Vanilla Mint Flavor, Talc, Chlorophyll, Stevia Leaf Extract.

CONTAINS: Fish and Soybeans.

Conforms to USP <2091> for weight.

ACTUAL SIZE

Healthy Aging Antioxidant Formula

Supplement Facts

Serving Size One Capsule

Amount Per Serving	
Coenzyme Q-10	100 mg*
resVida® trans-Resveratrol	30 mg*
Green Tea Extract (*Camellia sinensis*)(14% Polyphenols = 3.75 mg)	25 mg*
Turmeric Root Extract (*Curcuma longa*)(20% Curcuminoids = 2 mg)	10 mg*
Chios Mastiha Gum Powder (*Pistacia lentiscus*)	10 mg*
Lutemax® 2020 Lutein	2 mg*
Zeaxanthin (as Zeaxanthin Isomers)	400 mcg*

* Daily Value not established.

Other Ingredients: Cellulose, Gelatin, Corn Starch, Talc, Magnesium Stearate Vegetable Source, Silicon Dioxide.

Conforms to USP <2091> for weight.

Meets USP <2040> disintegration.

ACTUAL SIZE

Brain Health Complex

Supplement Facts

Serving Size One White Capsule

Amount Per Serving	
Choline (as Choline Bitartrate)	180 mg*
Ginkgo biloba Leaves Extract	120 mg*
(24% Ginkgo Flavone Glycosides = 28.8 mg)(6% Terpene Lactones = 7.2 mg)	
Phosphatidyl Choline (as Soy Lecithin)	20 mg*
Huperzine A	25 mcg*

* Daily Value not established.

Other Ingredients: Gelatin, Cellulose, Silica, Magnesium Stearate Vegetable Source, Titanium Dioxide (Natural Mineral Whitener).

Conforms to USP <2091> for weight.

Meets USP <2040> disintegration.

ACTUAL SIZE

Bone Building Complex

Supplement Facts

Serving Size One Beige Caplet

Amount Per Serving		% Daily Value
Calcium (as Calcium Carbonate)	600 mg	60%
Vitamin D (as Cholecalciferol D-3)	400 IU	100%
MBP®	40 mg	*

* Daily Value not established.

Other Ingredients: Cellulose, Magnesium Stearate Vegetable Source, Silica, Titanium Dioxide (Natural Mineral Whitener), Vegetable Acetoglycerides, Caramel Color, Ethyl Vanillin.

CONTAINS: Milk.

Conforms to USP <2091> for weight.

Meets USP <2040> disintegration.

ACTUAL SIZE

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.

No Artificial Colors. No Artificial Flavors. Gluten Free.

GLUTEN FREE

KEEP OUT OF REACH OF CHILDREN.

Store in a cool, dry place.

For More Information:

1-888-462-2548

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Distributed by:

General Nutrition Corporation

Pittsburgh, PA 15222

Essential Fatty Acids

Supplement Facts

Serving Size One Yellow Softgel

Amount Per Serving		% Daily Value
Calories	10	
Calories from Fat	15	
Total Fat	1.5 g	2%†
Total Omega-3s	942 mg	*
EPA (Eicosapentaenoic Acid)(Omega-3)	800 mg	*
Other Omega-3s	142 mg	*
GLA (gamma-Linolenic Acid)(Omega-6)	20 mg	*

† Percent Daily Values are based on a 2,000 calorie diet.

* Daily Value not established.

Other Ingredients: Fish Body Oil, Gelatin, Glycerin, Safflower Oil, Rosemary Extract (*Rosmarinus officinalis*).

CONTAINS: Fish (Pollock, Whiting, Anchovy, Sardine, Mackerel).

Conforms to USP <2091> for weight.

Meets USP <2040> disintegration.

ACTUAL SIZE

CurcuWIN™ is a trademark of OmniActive Health Technologies.

Lutemax® 2020 is a trademark of OmniActive Health Technologies.

MBP® is registered in the U.S.A. by MEGMILK SNOW BRAND Co., Ltd.

resVida® is a trademark of DSM.

"In a randomized, double-blind, placebo-controlled study of 112 healthy volunteers, subjects taking the GNC vitamin and mineral blends for six weeks experienced significant improvements in serum levels of certain key nutrients compared to a placebo and a basic multivitamin formula based upon multivariate statistical analyses of a group of 8 vitamins (thiamin, niacin, riboflavin, pantothenic acid, biotin, folic acid and vitamins B-6 and B-12) and key antioxidants and carotenoids (a group of beta-carotene, alpha-tocopherol, selenium, lutein and lycopene). Statistical improvements in SF-36 Vitality and Mental Health scores were also observed compared to placebo.

PHYSICIAN ENDORSED*

* This product is endorsed by the GNC Medical Advisory Board. This team of esteemed physicians utilizes their extensive medical knowledge and experience to aid in the creation of GNC premium products, helping you to achieve optimal health through comprehensive nutritional support so you can live your best life!

GNC

WOMEN'S ULTRA MEGA® 50 Plus

Dietary Supplement

VITAPAK® PROGRAM WITH CLINICALLY STUDIED MULTIVITAMIN*

- Antioxidants • Memory Support
- Heart Health • Bone Health

PHYSICIAN ENDORSED*

30 PACKS

NEW!

GNC

WOMEN'S ULTRA MEGA® 50 Plus

Achieve your daily nutritional goals with customized ingredients plus multivitamins that have more antioxidant power than ever, contain over 30 clinically studied ingredients – and are smaller and easier to swallow.

- **Women's Health**
  Contains a clinically studied women's multivitamin formula shown to work better than a basic multivitamin.*
- **Antioxidants**
  Helps protect against harmful free radicals that can destroy healthy cells and promote the cell aging process.*
- **Memory Support**
  Includes choline to support memory function and ginkgo biloba to support mental sharpness.*
- **Heart Health**
  Has EPA, which is important for cardiovascular and circulatory health and promotes healthy cholesterol and triglyceride levels.*
- **Bone Health**
  Features MBP®, which is clinically studied to support the body's natural ability to build and maintain healthy bones.*

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.


NEW!
GNC
WOMEN'S ULTRA MEGA® 50 Plus
Dietary Supplement
VITAPAK® PROGRAM WITH CLINICALLY STUDIED MULTIVITAMIN^
• Antioxidants • Memory Support
• Heart Health • Bone Health
PHYSICIAN ENDORSED*
30 PACKS
GNC
WOMEN'S ULTRA MEGA® 50 Plus
Women's Health
Antioxidants
Memory Support
Heart Health
Bone Health

WOMEN'S HEALTH
Contains a clinically studied women's multivitamin blend shown to work better than a basic multivitamin.

ANTIOXIDANTS
Helps protect against harmful free radicals that can destroy healthy cells and promote the cell aging process.*

MEMORY SUPPORT
Includes choline to support memory function and ginkgo biloba to support mental sharpness.

HEART HEALTH
Has EPA, which is important for cardiovascular and circulatory health and promotes healthy cholesterol and triglyceride levels.

BONE HEALTH
Features MBP®, which is clinically studied to support the body's natural ability to build and maintain healthy bones.

WOMEN'S 50 PLUS

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

*In a randomized, double-blind, placebo-controlled study of 112 healthy volunteers, subjects taking the GNC vitamin and mineral blends for six weeks experienced significant improvements in serum levels of certain key nutrients compared to a placebo and a leading multivitamin formula based upon multivariate statistical analyses of a group of B vitamins (thiamin, niacin, riboflavin, pantothenic acid, biotin, folic acid and vitamins B-6 and B-12) and key antioxidants and carotenoids (a group of beta-carotene, alpha-tocopherol, selenium, lutein and lycopene). Statistical improvements in SF-36 Vitality and Mental Health scores were also observed compared to placebo.

EXHIBIT 6

CODE 330220

Directions: As a dietary supplement, take the contents of one pack daily with food.

Each pack contains:

Women's Ultra Mega® Bone Density without Iron and Iodine

Supplement Facts

Serving Size Four Pink Caplets

Amount Per Serving		% Daily Value
Vitamin A (50% as beta-Carotene; 50% as Retinyl Acetate)	5000 IU	100%
Vitamin C (as Ascorbic Acid & Calcium Ascorbate)	200 mg	333%
Vitamin D (as Cholecalciferol D-3)	2000 IU	500%
Vitamin E (as Natural d-alpha Tocopheryl Acetate)	30 IU	100%
Vitamin K (as Phytonadione)	80 mcg	100%
Thiamin (Vitamin B-1) (as Thiamin Mononitrate)	50 mg	3333%
Riboflavin (Vitamin B-2)	50 mg	2941%
Niacin (as Niacin & Niacinamide)	50 mg	250%
Vitamin B-6 (as Pyridoxine Hydrochloride)	50 mg	2500%
Folic Acid	400 mcg	100%
Vitamin B-12 (as Cyanocobalamin)	50 mcg	833%
Biotin	300 mcg	100%
Pantothenic Acid (as Calcium d-Pantothenate)	50 mg	500%
Calcium (as Calcium Carbonate)	1000 mg	100%
Magnesium (as Magnesium Oxide)	250 mg	63%
Zinc (as Zinc Oxide)	15 mg	100%
Selenium (as L-Selenomethionine)	200 mcg	286%
Copper (as Cupric Oxide)	2 mg	100%
Manganese (as Manganese Sulfate)	2 mg	100%
Chromium (as Hydrolyzed Protein Chelate)	120 mcg	100%
Molybdenum (as Sodium Molybdate)	75 mcg	100%
MBP®	40 mg	*
Alpha-Lipoic Acid	25 mg	*
Choline (as Choline Bitartrate)	10 mg	*
Inositol	10 mg	*
Green Tea Leaf Extract (*Camellia sinensis*)	10 mg	*
Cranberry Concentrate (*Vaccinium macrocarpon*)	10 mg	*
Silica (as Silicon Dioxide)	4 mg	*
Boron (as Hydrolyzed Protein Chelate)	2 mg	*
Lutemax 2020™ Lutein	950 mcg	*
Lycopene	950 mcg	*
Zeaxanthin (as Zeaxanthin Isomers)	190 mcg	*
Astaxanthin	50 mcg	*
Vanadium (as Sodium Metavanadate)	10 mg	*

* Daily Value not established.

Other Ingredients: Cellulose, Titanium Dioxide (Natural Mineral Whitener), Carmine Color, Natural Vanilla Flavor, Vegetable Acetoglycerides, Sucralose.

CONTAINS: Fish and Milk.

ACTUAL SIZE

KRG

Menopause Formula

Supplement Facts

Serving Size One Brown Filled Capsule

Amount Per Serving	
Black Cohosh Root Extract (*Cimicifuga racemosa*)	160 mg*
Soy Isoflavone Concentrate (40% Isoflavones = 40 mg)	100 mg*

* Daily Value not established.

Other Ingredients: Cellulose, Gelatin, Maltodextrin.

CONTAINS: Soybeans.

WARNING: Contains Black Cohosh which is not to be used while pregnant or nursing.

Conforms to USP <2091> for weight. Meets USP <2040> disintegration.

ACTUAL SIZE

Fish Oil

Supplement Facts

Serving Size One Yellow Softgel Capsule

Amount Per Serving		% Daily Value
Calories	10	
Calories from Fat	10	
Total Fat	1 g	2%†
Cholesterol	10 mg	3%
Total Omega-3 Fatty Acids (including DHA/EPA)	300 mg	*

† Percent Daily Value based on a 2,000 calorie diet.
* Daily Value not established.

Other Ingredients: Fish Body Oil, Gelatin, Glycerin, Natural Lemon Flavor, Rosemary Leaf Extract (*Rosmarinus officinalis*), Vitamin E.

Potency verified by GNC procedure #5123. Conforms to USP <2091> for weight. Meets USP <2040> disintegration.

This product is regularly tested using AOAC international protocols for potency and purity by an independent, FDA-registered laboratory and found to be free of detectable levels of mercury, cadmium and lead.

ACTUAL SIZE

MBP® is registered in the U.S.A. by MEGMILK SNOW BRAND Co., Ltd.

Lutemax® 2020 is a trademark of OmniActive Health Technologies.

Evening Primrose Oil 1300

Supplement Facts

Serving Size One Yellow Softgel Capsule

Amount Per Serving		% Daily Value
Calories	10	
Calories from Fat	10	
Total Fat (as Evening Primrose Oil)(*Oenothera biennis*)	1 g	2%†
Polyunsaturated Fat	1 g	*

† Percent Daily Value based on a 2,000 calorie diet.
* Daily Value not established.

Other Ingredients: Gelatin, Glycerin, Enteric Coating (Cellulose, Sodium Alginate, Medium Chain Triglycerides, Oleic and Stearic Acid).

Typical fatty acid profile per Capsule:	
Linoleic Acid (LA)(omega-6)	910 mg
gamma-Linolenic Acid (GLA)(omega-6)	100 mg
Other Fatty Acids	280 mg

Potency verified by GNC procedure #5123. Conforms to USP <2091> for weight.

KEEP OUT OF REACH OF CHILDREN.
Store in a cool, dry place.

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.

No Artificial Colors, No Artificial Flavors, No Gluten, Yeast Free.

ACTUAL SIZE

For More Information:
1-888-462-2548

SHOP NOW @ GNC.COM

Distributed by:
General Nutrition Corporation
Pittsburgh, PA 15222 USA

OUR QUALITY COMMITMENT TO YOU

Since 1935, our mission as the industry leader has been to provide you with the highest-quality nutritional supplements. We continue to stand behind this mission. If you're not 100% satisfied with your purchase, return the unused portion of the product with your receipt within 30 days and we'll either refund your money or find you a replacement product that is right for you.

GNC

WOMEN'S ULTRA MEGA® Menopause

Dietary Supplement

VITAPAK® PROGRAM

- Clinically studied multivitamin^ with 2,000 IU vitamin D-3
- Enhanced formula to help manage hot flashes and night sweats*
- Supports heart and cholesterol health with omega-3s*
- Helps build and maintain bone density with 1,000 mg calcium*

30 PACKS

GNC

WOMEN'S ULTRA MEGA® Menopause

GNC Women's Ultra Mega® Menopause Vitapak® Program conveniently combines nutrients and special ingredients designed to support a woman's overall health as she experiences mid-life changes.

Women's Ultra Mega® Bone Density without Iron and Iodine
Our premium timed-release, clinically studied^ formula includes vitamins and minerals designed specifically to emphasize the key nutrients for bone health. Features 1,000 mg of calcium, 2,000 IU of vitamin D-3 and 40 mg of clinically studied MBP®, a protein complex derived from milk, shown to support natural bone building.* Enhanced with a broad spectrum of cell-protecting antioxidant nutrients and vitamin K, copper, zinc and manganese which are essential nutrients involved in the formation of the bone matrix.*

Menopause Formula
An advanced isoflavone formula that features standardized soy isoflavones. Natural soy isoflavones act as mild estrogens and may help manage hot flashes and night sweats associated with menopause.* This formula is enhanced with black cohosh, a popular herb studied in German clinical trials and frequently recommended for hot flashes.

Evening Primrose Oil
Supplies a natural source of the omega-6 fatty acid gamma-linolenic acid (GLA). GLA provides dietary support for cardiovascular system function, healthy blood lipid levels and healthy joint function.* It also helps to maintain smooth, healthy-looking skin and acts as a precursor to prostaglandins, hormone-like substances that help to regulate the body processes, including hormone balance.*

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

GNC

WOMEN'S ULTRA MEGA®

Menopause

Dietary Supplement

VITAPAK® PROGRAM

- Clinically studied multivitamin^ with 2,000 IU vitamin D-3
- Enhanced formula to help manage hot flashes and night sweats*
- Supports heart and cholesterol health with omega-3s*
- Helps build and maintain bone density with 1,000 mg calcium*

30 PACKS

PHYSICIAN ENDORSED*

EXHIBIT 7

Lutemax 2020™ is a trademark of OmniActive Health Technologies.

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.

Conforms to USP <2091> for weight.
Meets USP <2040> disintegration.

KEEP OUT OF REACH OF CHILDREN.
Store in a cool, dry place.

For More Information:
1-888-462-2548

SHOP NOW @ GNC.COM

Distributed by:
General Nutrition Corporation
Pittsburgh, PA 15222

One Per Day

SCAN & LEARN MORE

† Compared to the leading women's 50 Plus multivitamin brand.

‡ Emerging research suggests that adequate daily vitamin D intake may play a role in supporting breast and colon health.

GNC QUALITY COMMITMENT

For more than 78 years, GNC has been the leader in the development of superior nutritional supplements. Our products are produced using only fresh, high-quality ingredients and are manufactured under the strictest quality controls.

GNC GUARANTEE

If you are not 100% completely satisfied, return the unused portion of the product with your receipt to a GNC store within 30 days. Our trained sales staff will either refund your purchase price or, if you prefer, assist you in finding a replacement product to help you LIVE WELL.

Please recycle this box.

WOMEN'S ULTRA MEGA® 50 PLUS ONE DAILY

GNC Women's Ultra Mega® 50 Plus One Daily is a premium multivitamin providing 39 important nutrients essential for overall wellness, plus unique blends scientifically formulated to support the specific health needs of women, in one ultra concentrated pill.

◆This product is endorsed by the GNC Medical Advisory Board. This team of esteemed physicians utilizes their extensive medical knowledge and experience to aid in the creation of GNC premium products, helping you to achieve optimal health through comprehensive nutritional support so you can live your best life!

HOW DOES YOUR MULTIVITAMIN COMPARE?

Ultra Concentrated Technology for Greater Benefits*	GNC Women's Ultra Mega® 50 Plus One Daily Premium Multivitamin	Leading Women's 50 Plus Multivitamin†
Nutrients Delivered in One Caplet	39	31
Nutrients with at Least 100% Daily Value	18	9
At Least 100% DV of 8 Key B Vitamins	✔	–
More Vitamin B-12 Important for Neurological Function and Red Blood Cell Formation*	✔	–
More Vitamin C to Support Natural Resistance*	150 mg	120 mg
Supports Breast and Colon Health with More Vitamin D‡*	1200 IU	800 IU
Customized Women's Health Blends	✔	–
With Ginkgo, Phosphatidylserine, Choline and Inositol to Support Brain Health*	✔	–
Lutein for Eye Health Support*	✔	–
Cranberry for Urinary Tract Support*	✔	–
Supports Healthy Skin Structure Collagen and Silica and Protects Against Free Radicals with Zeaxanthin*	✔	–

***Ultra Concentrated Technology:** Using cutting-edge product development processes, GNC Women's Ultra Mega® 50 Plus One Daily Multivitamin was developed to deliver more nutrients in one standard size pill for greater benefits.

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

GNC

WOMEN'S ULTRA MEGA® 50 Plus One Daily

Dietary Supplement

ONE PER DAY MULTIVITAMIN

Ultra Concentrated with 39 important nutrients.

- Provides 18 vitamins & minerals at 100% daily value or more
- Strengthens bones with calcium and vitamin D-3*
- B vitamins to support energy production and metabolism *

PHYSICIAN ENDORSED◆

One Per Day
60 CAPLETS

CODE 179722 HOG

Directions: As a dietary supplement, take one caplet daily with food.

Supplement Facts

Serving Size One Caplet

Amount Per Serving		% Daily Value
Vitamin A (as Retinyl Acetate)	3500 IU	70%
Vitamin C (as Ascorbic Acid)	150 mg	250%
Vitamin D (as Cholecalciferol D-3)	1200 IU	300%
Vitamin E (as Natural d-alpha Tocopheryl Succinate)	35 IU	117%
Vitamin K (as Phytonadione)	60 mcg	75%
Thiamin (Vitamin B-1)(as Thiamin Mononitrate)	4.95 mg	330%
Riboflavin (Vitamin B-2)	3.74 mg	220%
Niacin (as Niacinamide)	22 mg	110%
Vitamin B-6 (as Pyridoxine Hydrochloride)	6.6 mg	330%
Folic Acid	600 mcg	150%
Vitamin B-12 (as Cyanocobalamin)	110 mcg	1833%
Biotin	300 mcg	100%
Pantothenic Acid (as Calcium d-Pantothenate)	16.5 mg	165%
Calcium (as Calcium Carbonate and Dicalcium Phosphate)	500 mg	50%
Iron (as Ferrous Fumarate)	8 mg	44%
Phosphorus (as Dicalcium Phosphate)	15 mg	2%
Iodine (as Potassium Iodide)	150 mcg	100%
Magnesium (as Magnesium Oxide)	50 mg	13%
Zinc (as Zinc Oxide)	30 mg	200%
Selenium (as Sodium Selenite)	70 mcg	100%
Copper (as Cupric Oxide)	2 mg	100%
Manganese (as Manganese Sulfate)	2 mg	100%
Chromium (as Hydrolyzed Protein Chelate)	200 mcg	167%
Molybdenum (as Hydrolyzed Protein Chelate)	75 mcg	100%
Chloride (as Potassium Chloride)	72 mg	2%
Potassium (as Potassium Chloride)	80 mg	2%
Brain Health Blend		
Ginkgo biloba Leaf Extract	10 mg	*
Phosphatidyl Serine	2.5 mg	*
Choline (as Choline Bitartrate)	2.5 mg	*
Inositol	2.5 mg	*
Eye Health Support		
Lutemax 2020™ Lutein	1 mg	*
Urinary Tract & Women's Health Blend		
Cranberry Fruit Concentrate	10 mg	*
Boron (as Hydrolyzed Protein Chelate)	150 mcg	*
Tin (as Stannous Chloride)	10 mcg	*
Vanadium (as Vanadyl Sulfate)	10 mcg	*
Nickel (as Nickel Sulfate)	5 mcg	*
Skin Structure & Antioxidant Support Blend		
Collagen Hydrolysate	5 mg	*
Silica (as Silicon Dioxide)	2 mg	*
Zeaxanthin (as Zeaxanthin Isomers)	200 mcg	*

* Daily Value not established.

Other Ingredients: Cellulose, Titanium Dioxide, Vegetable Acetoglycerides, Cool Mint Vanilla Flavor, Carmine Color, Sucralose.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.


GNC
WOMEN'S
ULTRA MEGA®
50 Plus One Daily
Dietary Supplement
ONE PER DAY MULTIVITAMIN
Ultra Concentrated with 39 important nutrients
• Provides 18 vitamins & minerals at a 100% daily value or more
• Supports healthy aging*
PHYSICIAN ENDORSED*
One Per Day
60 CAPLETS

DOE 179722

Directions: As a dietary supplement, take one caplet daily with food.

Supplement Facts

Serving Size One Caplet

Amount Per Serving		% Daily Value
Vitamin A (as Retinyl Acetate)	3500 IU	70%
Vitamin C (as Ascorbic Acid)	150 mg	250%
Vitamin D (as Cholecalciferol D-3)	1200 IU	300%
Vitamin E (as Natural d-alpha Tocopheryl Succinate)	35 IU	117%
Vitamin K (as Phytonadione)	60 mcg	75%
Thiamin (Vitamin B-1) (as Thiamin Mononitrate)	4.95 mg	330%
Riboflavin (Vitamin B-2)	3.74 mg	220%
Niacin (as Niacinamide)	22 mg	110%
Vitamin B-6 (as Pyridoxine Hydrochloride)	6.6 mg	330%
Folic Acid	600 mcg	150%
Vitamin B-12 (as Cyanocobalamin)	110 mcg	1833%
Biotin	300 mcg	100%
Pantothenic Acid (as Calcium d-Pantothenate)	16.5 mg	165%
Calcium (as Calcium Carbonate & Dicalcium Phosphate)	500 mg	50%
Iron (as Ferrous Fumarate)	8 mg	44%
Phosphorus (as Dicalcium Phosphate)	15 mg	2%
Iodine (as Potassium Iodide)	150 mcg	100%
Magnesium (as Magnesium Oxide)	50 mg	13%
Zinc (as Zinc Oxide)	30 mg	200%
Selenium (as Sodium Selenite)	70 mcg	100%
Copper (as Cupric Oxide)	2 mg	100%
Manganese (as Manganese Sulfate)	2 mg	100%
Chromium (as Hydrolyzed Protein Chelate)	200 mcg	167%
Molybdenum (as Hydrolyzed Protein Chelate)	75 mcg	100%
Chloride (as Potassium Chloride)	72 mg	2%
Potassium (as Potassium Chloride)	80 mg	2%
Brain Health Blend		
Ginkgo biloba Leaf Extract	10 mg	*
Phosphatidylserine	2.5 mg	*
Choline (as Choline Bitartrate)	2.5 mg	*
Inositol	2.5 mg	*
Eye Health Support		
Lutemax® 2020 Lutein	1 mg	*
Urinary Tract & Women's Health Blend		
Cranberry Fruit Concentrate	10 mg	*
Boron (as Hydrolyzed Protein Chelate)	150 mcg	*
Tin (as Stannous Chloride)	10 mcg	*
Vanadium (as Vanadyl Sulfate)	10 mcg	*
Nickel (as Nickel Sulfate)	5 mcg	*
Skin Structure & Antioxidant Support Blend		
Collagen Hydrolysate	5 mg	*
Silica (as Silicon Dioxide)	2 mg	*
Zeaxanthin (as Zeaxanthin Isomers)	200 mcg	*

* Daily Value not established.

Other Ingredients: Cellulose, Titanium Dioxide, Vegetable Acetoglycerides, Cool Mint Vanilla Flavor, Carmine Color, Sucralose.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.

Lot No./Best By:

No Artificial Colors, No Artificial Flavors, No Wheat, Gluten Free, No Dairy, Yeast Free.
CurcuWIN™ and Lutemax® 2020 trademarks belong to OmniActive Health Technologies.

KEEP OUT OF REACH OF CHILDREN.
Store in a cool, dry place.

For More Information:
1-888-462-2548

SHOP NOW @ GNC.COM

GLUTEN FREE

Distributed by:
General Nutrition Corporation
Pittsburgh, PA 15222

PHYSICIAN ENDORSED*

*This product is endorsed by the GNC Medical Advisory Board. This team of esteemed physicians utilizes their extensive medical knowledge and experience to aid in the creation of GNC premium products, helping you to achieve optimal health through comprehensive nutritional support so you can live your best life!

^In a randomized, double-blind, placebo-controlled study of 112 healthy volunteers, subjects taking the GNC vitamin and mineral blends for six weeks experienced significant improvements in serum levels of certain key nutrients compared to a placebo and a leading multivitamin formula based upon multivariate statistical analyses of a group of B vitamins (thiamin, niacin, riboflavin, pantothenic acid, biotin, folic acid and vitamins B-6 and B-12) and key antioxidants and carotenoids (a group of beta-carotene, alpha-tocopherol, selenium, lutein and lycopene). Statistical improvements in SF-36 Vitality and Mental Health scores were also observed compared to placebo.

GNC QUALITY COMMITMENT

For more than 79 years, GNC has been the leader in the development of superior nutritional supplements. Our products are produced using only fresh, high-quality ingredients and are manufactured under the strictest quality controls.

GNC

WOMEN'S ULTRA MEGA® 50 Plus

More antioxidant power than ever and over 30 clinically studied ingredients in every formula – all in smaller, easier-to-swallow pills.

- **Women's Health**
  Contains a clinically studied women's multivitamin shown to work better than a basic multivitamin.^
- **Antioxidants**
  Packed with antioxidants to help protect against harmful free radicals that can destroy healthy cells and promote cell aging.*
- **Bone Health**
  Contains a potent calcium and vitamin D complex to support strong bones.*
- **Skin Support**
  Includes lutein to support skin hydration and hyaluronic acid, which plays a role in maintaining skin elasticity.*

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

GNC

NEW! SMALLER PILLS

WOMEN'S ULTRA MEGA® 50 Plus

Dietary Supplement

CLINICALLY STUDIED MULTIVITAMIN^

- Antioxidants
- Bone Health
- Skin Support

PHYSICIAN ENDORSED*

Timed-Release
60 CAPLETS

CODE 202545 AQG

Directions: As a dietary supplement, take two caplets daily with food.

Supplement Facts

Serving Size Two Caplets
Servings Per Container 30

Amount Per Serving	% Daily Value
Vitamin A (50% as beta-Carotene & 50% Retinyl Acetate) 5000 IU	100%
Vitamin C (as Ascorbic Acid & Calcium Ascorbate) 200 mg	333%
Vitamin D (as Cholecalciferol D-3) 1600 IU	400%
Vitamin E (as Natural d-alpha Tocopheryl Acetate) 30 IU	100%
Vitamin K (as Phytonadione) 80 mcg	100%
Thiamin (Vitamin B-1)(as Thiamin Mononitrate) 50 mg	3333%
Riboflavin (Vitamin B-2) 50 mg	2941%
Niacin (as Niacinamide & Niacin) 50 mg	250%
Vitamin B-6 (as Pyridoxine Hydrochloride) 50 mg	2500%
Folic Acid 400 mcg	100%
Vitamin B-12 (as Cyanocobalamin) 50 mcg	833%
Biotin 300 mcg	100%
Pantothenic Acid (as Calcium d-Pantothenate) 50 mg	500%
Calcium (as Calcium Carbonate & Calcium Ascorbate) 500 mg	50%
Iodine (as Potassium Iodide) 150 mcg	100%
Magnesium (as Magnesium Oxide) 50 mg	13%
Zinc (as Zinc Oxide) 15 mg	100%
Selenium (as L-Selenomethionine) 200 mcg	286%
Copper (as Copper Sulfate) 2 mg	100%
Manganese (as Manganese Sulfate) 2 mg	100%
Chromium (as Chromium Chloride) 120 mcg	100%
Molybdenum (as Sodium Molybdate) 75 mcg	100%
Super Antioxidant Blend	
alpha-Lipoic Acid 25 mg	*
Lutemax® 2020 Lutein 2 mg	*
Lycopene 1 mg	*
Turmeric Root Extract (CurcuWIN™)(*Curcuma longa*)(Standardized to Curcuminoids) 500 mcg	*
Zeaxanthin (as Zeaxanthin Isomers) 400 mcg	*
Astaxanthin (from *Haematococcus pluvialis*) 50 mcg	*
beta-Cryptoxanthin 10 mcg	*
Brain & Circulatory Support	
Choline (as Choline Bitartrate) 10 mg	*
Inositol 10 mg	*
Ginkgo biloba Powder 5 mg	*
Bacopa monnieri Leaf Extract 4 mg	*
Boron (as Sodium Borate) 2 mg	*
Phosphatidyl Serine 1 mg	*
Vanadium (as Sodium Metavanadate) 10 mcg	*
Eye & Skin Health Complex	
Silica (as Silicon Dioxide) 4 mg	*
Black Currant Fruit Extract (*Ribes nigrum*) 2.5 mg	*
Blueberry Fruit Powder (*Vaccinium angustifolium*) 2.5 mg	*
Cranberry Fruit Concentrate (*Vaccinium macrocarpon*) 2.5 mg	*
Bilberry Fruit Powder (*Vaccinium myrtillus*) 2.5 mg	*
Elderberry Fruit Powder (*Sambucus nigra*) 2.5 mg	*
Hyaluronic Acid (as Sodium Hyaluronate) 2 mg	*
Resveratrol 1 mg	*
Grape Seed Extract (*Vitis vinifera*)(Standardized to Polyphenols) 1 mg	*

* Daily Value not established.

Other Ingredients: Cellulose, Stearic Acid Vegetable Source, Magnesium Stearate Vegetable Source, Titanium Dioxide (Natural Mineral Whitener), Natural Vanilla Mint Flavor, Talc, Chlorophyll, Stevia Leaf Extract.
CONTAINS: Fish and Soybeans.
WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery.
Conforms to USP <2091> for weight.


GNC
WOMEN'S
ULTRA MEGA®
50 Plus
Dietary Supplement
CLINICALLY STUDIED MULTIVITAMIN*
• Antioxidants
• Bone Health*
• Skin Support*
PHYSICIAN
ENDORSED*
Timed-Release
60 CAPLETS

CODE 2022545 BRG
Directions: As a dietary supplement, take two caplets daily with food.

Supplement Facts

Serving Size Two Caplets
Servings Per Container 30

Amount Per Serving	% Daily Value
Vitamin A ... 5000 IU	100%
(50% as beta-Carotene & 50% Retinyl Acetate)	
Vitamin C ... 200 mg	333%
(as Ascorbic Acid & Calcium Ascorbate)	
Vitamin D (as Cholecalciferol D-3) ... 1600 IU	400%
Vitamin E ... 30 IU	100%
(as Natural d-alpha Tocopheryl Acetate)	
Vitamin K (as Phytonadione) ... 80 mcg	100%
Thiamin ... 50 mg	3333%
(Vitamin B-1)(as Thiamin Mononitrate)	
Riboflavin (Vitamin B-2) ... 50 mg	2941%
Niacin (as Niacinamide & Niacin) ... 50 mg	250%
Vitamin B-6 ... 50 mg	2500%
(as Pyridoxine Hydrochloride)	
Folic Acid ... 400 mcg	100%
Vitamin B-12 (as Cyanocobalamin) ... 50 mcg	833%
Biotin ... 300 mcg	100%
Pantothenic Acid ... 50 mg	500%
(as Calcium d-Pantothenate)	
Calcium ... 500 mg	50%
(as Calcium Carbonate & Calcium Ascorbate)	
Iodine (as Potassium Iodide) ... 150 mcg	100%
Magnesium (as Magnesium Oxide) ... 50 mg	13%
Zinc (as Zinc Oxide) ... 15 mg	100%
Selenium (as L-Selenomethionine) ... 200 mcg	286%
Copper (as Copper Sulfate) ... 2 mg	100%
Manganese (as Manganese Sulfate) ... 2 mg	100%
Chromium (as Chromium Chloride) ... 120 mcg	100%
Molybdenum (as Sodium Molybdate) ... 75 mcg	100%

Amount Per Serving	% Daily Value
Super Antioxidant Blend	
alpha-Lipoic Acid ... 25 mg	*
Lutemax® 2020 Lutein ... 2 mg	*
Lycopene ... 1 mg	*
Turmeric Root Extract (CurcuWIN™) ... 500 mcg	*
(*Curcuma longa*)(Standardized to Curcuminoids)	
Zeaxanthin (as Zeaxanthin Isomers) ... 400 mcg	*
Astaxanthin ... 50 mcg	*
(from *Haematococcus pluvialis*)	
beta-Cryptoxanthin ... 10 mcg	*
Brain & Circulatory Support	
Choline (as Choline Bitartrate) ... 10 mg	*
Inositol ... 10 mg	*
Ginkgo biloba Leaf Powder ... 5 mg	*
Bacopa monnieri Leaf Extract ... 4 mg	*
Boron (as Sodium Borate) ... 2 mg	*
Phosphatidylserine ... 1 mg	*
Vanadium (as Sodium Metavanadate) ... 10 mcg	*
Eye & Skin Health Complex	
Silica (as Silicon Dioxide) ... 4 mg	*
Black Currant Fruit Extract ... 2.5 mg	*
(*Ribes nigrum*)	
Blueberry Fruit Powder ... 2.5 mg	*
(*Vaccinium angustifolium*)	
Cranberry Fruit Concentrate ... 2.5 mg	*
(*Vaccinium macrocarpon*)	
Bilberry Fruit Powder ... 2.5 mg	*
(*Vaccinium myrtillus*)	
Elderberry Fruit Powder ... 2.5 mg	*
(*Sambucus nigra*)	
Hyaluronic Acid (as Sodium Hyaluronate) ... 2 mg	*
Resveratrol ... 1 mg	*
Grape Seed Extract ... 1 mg	*
(*Vitis vinifera*)(Standardized to Polyphenols)	

* Daily Value not established.

Other Ingredients: Cellulose, Stearic Acid Vegetable Source, Magnesium Stearate Vegetable Source, Titanium Dioxide (Natural Mineral Whitener), Natural Vanilla Mint Flavor, Talc, Chlorophyll, Stevia Leaf Extract.

Contains: Fish and Soybeans.

WARNING: Consult your physician prior to using this product if you have pregnancy, nursing, taking medications, or have a medical condition. Keep out of reach of children. Do not use if safety seal is broken or missing. Store in a cool, dry place.

EXHIBIT 8

DECLARATION OF WYATT A. LISON

PURSUANT TO CALIFORNIA CIVIL CODE § 1780(d)

I, Wyatt A. Lison, declare as follows:

1. I am a partner with the law firm Feinstein Doyle Payne & Kravec, LLC, counsel for Plaintiffs Christina Labajo, Howard Clark and Berry Saizon in this action. I am admitted to practice law in California and before this Court, and am a member in good standing of the State Bar of California. This declaration is made pursuant to California Civil Code § 1780(d). I make this declaration based on my research of public information and also upon personal knowledge, and if called upon to do so, could and would testify competently thereto.

2. Based on my firm's investigation, Defendant General Nutrition Corporation conducts business within this County. Specifically, based on my firm's investigation, General Nutrition Corporation maintains stores within this county, and sells some of the products at issue at its stores in San Francisco County, California.

I declare under penalty of perjury under the laws of the United States and of the State of California this 12th day of March, 2019, in Pittsburgh, Pennsylvania that the forgoing is true and correct.

Wyatt A. Lison

EXHIBIT 9

Feinstein Doyle Payne & Kravec LLC

429 Fourth Avenue
Law & Finance Building, Suite 1300
Pittsburgh, PA 15219
T: 412.281.8400
F: 412.281.1007

29 Broadway, 24th Floor
New York, NY 10006-3205
T: 212.952.0014
www.fdpklaw.com

Writers' Emails:
jkravec@fdpklaw.com
wpayne@fdpklaw.com

November 17, 2017

via Certified Mail/Return Receipt Requested

Ken Martindale
Chief Executive Officer
GNC Holdings, Inc.
300 Sixth Avenue
Pittsburgh, PA 15222

Ken Martindale, CEO
General Nutrition Corporation
c/o National Registered Agents, Inc.
818 West Seventh Street - Suite 930
Los Angeles, California 90017

Re: Unlawful, False, and Materially Misleading Labeling and Marketing of Supplements by GNC in Violation of State and Federal Law

Dear Mr. Martindale:

We represent Howard Clark, Christina Labajo, Marcia Nupp (our "Clients"), as well as potentially classes of California and New York consumers, who purchased certain GNC Holdings, Inc. and General Nutrition Corporation (collectively, "GNC") brand supplements[1] (the "Supplements") that are unlawfully, misleadingly, and deceptively labeled in violation of California and New York law and U.S. Food and Drug Administration ("FDA") regulations. Specifically, GNC unlawfully and misleadingly labels certain of the Supplements as treating or mitigating heart disease, reducing inflammation, treating or mitigating hypercholesterolemia,

[1] At least the following Supplements are mislabeled as described in this letter: GNC Healthy Cholesterol Formula (attached hereto as Exhibit 1), GNC Policosanol (200 mg) (attached hereto as Exhibit 2), GNC Ultra 35 Probiotic Complex (attached hereto as Exhibit 3), GNC Probiotic Solutions Adults 50 Plus (attached hereto as Exhibit 4), GNC Women's Ultra Mega 50 Plus – Vitapak (attached hereto as Exhibit 5), GNC Women's Ultra Mega Menopause (attached hereto as Exhibit 6), GNC Healthy Blood Sugar Formula (attached hereto as Exhibit 7), GNC Healthy Blood Pressure Formula (attached hereto as Exhibit 8), GNC Pycnogenol (50 mg) (attached hereto as Exhibit 9), GNC Quercetin (500 mg) (attached hereto as Exhibit 10), GNC Selenium (200 mcg) (attached hereto as Exhibit 11), GNC Ultra Zinc Lozenges (attached hereto as Exhibit 12), GNC CoQ-10 (100 mg) (attached hereto as Exhibit 13), GNC CoQ-10 (200 mg) (attached hereto as Exhibit 14), GNC CoQ-10 (400 mg) (attached hereto as Exhibit 15), GNC Women's Ultra Mega 50 Plus (Individual Bottle) (attached hereto as Exhibit 16). To the extent that GNC sells additional products making these same or similar claims, such products are also unlawfully, misleadingly, and deceptively labeled in violation of California and New York law and U.S. Food and Drug Administration regulations, and hereby included in this demand letter.

treating or mitigating oxidative stress, fighting disease and/or augmenting statin therapies, all of which are disease claims which are unlawful and misleading for dietary supplements (the "Disease Claims").

This letter shall serve as our Clients' pre-litigation notice and demand in accordance with the requirements of California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750–85, N.Y. U.C.C. § 2-313 and all other states' laws that require a pre-suit demand. Accordingly, this letter is to demand that, in California and New York, GNC immediately cease the false and misleading labeling and advertising described herein; refrain from using labels that do not comply with California, New York, and federal law; and pay damages to consumers who purchased the Supplements. If you do not do so within thirty (30) days of receipt of this letter, one or more of our Clients may bring claims for deceptive practices under the CLRA, Cal. Civ. Code §§ 1750–85, for breach of express warranty under N.Y. U.C.C. § 2-313, and/or for deceptive business practices and false advertising under New York's General Business Law §§ 349 and 350, among other claims. All further communications intended for our Clients must be directed through this office.

Mr. Clark purchased the following Supplements near his home in San Francisco, California within the past three years:

- GNC Healthy Cholesterol Formula
- GNC Probiotic Solutions Adults 50 Plus
- GNC Ultra 35 Probiotic Complex
- GNC Healthy Blood Sugar Formula
- GNC Pycnogenol
- GNC Ultra Zinc Lozenges
- GNC CoQ-10 100 mg

Ms. Labajo purchased the GNC's Women's Ultra Mega Menopause near her home in Ontario, California within the past three years.

Ms. Nupp purchased at least the following Supplements near her home in Rochester, New York within the past four years:

- GNC Healthy Cholesterol Formula
- GNC Policosanol
- GNC Probiotic Solutions Adults 50 Plus
- GNC Healthy Blood Sugar Formula
- GNC Healthy Blood Pressure Formula
- GNC Pycnogenol
- GNC Ultra Zinc Lozenges

Had our Clients known that the Supplements marketed as dietary supplements were actually unapproved drugs and that the advertised claims were actually Disease Claims that were required to be evaluated and approved as safe and effective for the advertised purposes by the FDA

prior to being sold, but had not gone through the pre-approval process so the advertised treatment, cure, disease prevention, mitigation and augmentation claims were unapproved and the attendant FDA required drug fact disclosures were concealed from them, this would have changed our Clients' purchasing decisions.

I. BACKGROUND

A. History of Biologics and Drug Laws

The purpose of the U.S. Food, Drug, and Cosmetic Act ("FDCA"), FDA regulations and oversight is consumer protection. Congress passed the first Drug Importation Act in 1848 in response to the publication of a book documenting the problem with the American drug market, and high mortality of soldiers injured in the Mexican-American War. The Drug Importation Act prohibited the importation of unsafe or adulterated drugs.

Later, after many children died from being administered tainted versions of newly-invented cures for diseases such as diphtheria, Congress passed the Biologics Control Act of July 1, 1902. This law mandated licensing of establishments to manufacture and sell vaccines and other antitoxins sold in interstate commerce, and supervision of the manufacturing of such items by a qualified scientist. An agency called the Hygienic Laboratory, the predecessor of today's National Institutes of Health, was authorized to inspect licensed establishments and to sample biologics for purity and potency. The oversight of biologics was transferred to the FDA in 1972.

In 1906, Congress passed the Pure Food and Drugs Act to prohibit the sale of adulterated or misbranded drugs in interstate commerce. Amongst other things, it identified official standards for drugs, and required the labeling of the presence of select addicting substances such as morphine, heroin and cocaine. In 1938, Congress enacted the FDCA after 107 deaths were caused by a new "wonder drug" called Elixir Sulfanilamide that, despite the catastrophic results of its use, the company could not be prosecuted under then-existing laws for anything other than "misbranding" the product.

Amongst other things, the newly-enacted FDCA required drug manufacturers to prove to the FDA that a new drug was safe before it could be marketed, which was the birth of the "new drug application" or NDA. In enacting the FDCA, Congress sought to strike a balance between consumers' desire to pursue new remedies for ailments, and the introduction of effective drugs into the marketplace. It was this interplay between consumers' interest in effective cures and evolving science that all new drugs have to bear adequate directions for safe use and warnings whenever necessary. Within 2 months of the FDCA's enactment, the FDA determined that some drugs could not be labeled for safe self-use, but required supervision for individualized use by a physician or dentist which gave rise to the first prescription regulations. The requirement that certain drugs only be provided pursuant to a prescription was later codified in an amendment to the FDCA in 1951.

B. Drug Pre-Approval Process

In October 1962, Congress passed the Kefauver-Harris Drug Amendments to the FDCA, in part as a result of congressional investigations into drug approval after reports of the birth of thousands of malformed babies from the use of thalidomide that was prescribed for sleeplessness. The Kefauver-Harris Amendments required that before marketing a drug, drug companies had to provide the FDA substantial evidence of effectiveness and safety for the intended use of the drug. Such evidence had to be based on controlled studies to ensure efficacy, and the FDA was required to approve the company's marketing application before the drug could be marketed. Since the enactment of the Kefauver-Harris Amendments, consumers have become reliant on the FDA's pre-approval process to be assured that products labeled as drugs have been proven to be safe and effective for their marketed purposes.

Still today the FDCA mandates that, "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." 21 U.S.C. § 355. Under the FDCA, a "drug" is defined as, amongst other things, any "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal," and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B) and (C). Conversely, a dietary supplement is a product (other than tobacco) intended to supplement that diet that bears or contains a dietary ingredient such as a vitamin, mineral, herb or other botanical, or amino acid. *Id.* at 321(ff). If a dietary supplement product has drug properties, it must be approved and labeled as a drug.

There are two ways to have a substance approved as a new drug.[2] First, a company can submit a new drug application ("NDA") to introduce a new drug to the market. *See* 21 U.S.C. § 255(b). A company submitting a NDA bears the responsibility to test it and submit evidence that it is safe and effective. Such testing often includes clinical trials to prove both safety and efficacy. Alternatively, a company can submit an abbreviated new drug ("ANDA") application for the review and approval of generic drugs. *Id.* at 255(j).

The NDA and ANDA play an essential role in ensuring that drugs are both safe and effective for their intended uses, and that consumers of drugs are provided the FDA required drug fact disclosures, discussed *infra*. Manufacturers of drugs that lack required approval have not provided the FDA with evidence demonstrating that their products are safe and effective for their intended, *i.e.*, marketed, uses. The sale of such unapproved drugs is what the FDA has described as "Health Fraud" which the FDA terms a "direct health hazard," "indirect health hazard" and "major economic cheat" to consumers who rely on products making drug claims as having been proven to the FDA's satisfaction that they are both safe and effective to provide the advertised benefits as explained more fully in Section I.D., *infra*.

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[2] Over the counter ("OTC") drugs marketed in the United States prior to May 11, 1972 can also be approved through the OTC Monograph Process.

C. Dietary Supplement Labeling

A food, including dietary supplements, is misbranded if it characterizes the relationship of a nutrient to a disease or health-related condition unless made in accordance with the FDCA. 21 U.S.C. § 343(r)(1). A statement characterizing the relationship of a nutrient to a disease or health-related condition on a dietary supplement may be made only if

> the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.

21 U.S.C. § 343(r)(6)(A). Such structure/function claim may only be made if "the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading." *Id.* § 343(r)(6)(B). "A statement [for a dietary supplement] under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6)(C).

"For purposes of 21 U.S.C. 343(r)(6), a 'disease' is damage to an organ, part, structure, or system of the body such that it does not function properly (*e.g.,* **cardiovascular disease**), or a state of health leading to such dysfunctioning (*e.g.*, hypertension); except that diseases resulting from essential nutrient deficiencies (*e.g.*, scurvy, pellagra) are not included in this definition." 21 C.F.R. 101.93(g) (emphasis added). A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

> (i) Has an effect on a specific disease or class of diseases;
>
> (ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;
>
> (iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;
>
> (iv) Has an effect on a disease or diseases through one or more of the following factors:
>
> (A) The name of the product;
> (B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;
> (C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or

packaging, inappropriate prominence, or lack of relationship to the product's express claims;
(D) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or
(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(x) Otherwise suggests an effect on a disease or diseases.

21 C.F.R. § 101.93(g)(2). Claims that a product can mitigate, treat, cure, or prevent disease require prior approval by the FDA and may be made only for products that are approved drug products, or for foods with FDA-approved "health claims." 21 C.F.R. 101.93 (f); *see also Gallagher v. Bayer AG*, 2015 WL 1056480 at *7, fn. 9 (N.D. Cal. March 10, 2015) (*citing* 65 Fed. Reg. 1000, 1002, "an otherwise acceptable structure/function claim might nevertheless be false or misleading for other reasons, causing the product to be misbranded under section 403(a)(1) of the act.").

D. Health Fraud

Health Fraud is the deceptive promotion, advertisement, distribution or sale of substances represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purpose. *See* FDA Compliance Policy Guide 120.500 Health Fraud (available online at https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073838.htm).[3] Such scientific proof of safety and efficacy must be submitted to, accepted by and approved by the FDA before the product can be marketed with drug claims. 21 U.S.C. § 355. Health Fraud is one of the FDA's highest enforcement priorities when it involves a direct risk of health, and is classified by the FDA as a "major economic cheat" even when a person's health is not at risk. *See* FDA Compliance Policy Guide 120.500 Health Fraud. Moreover, even if the Health Fraud does not pose a direct risk to a person's health, it can be an

[3] Such practices may be deliberate, or done without adequate knowledge or understanding of the article. FDA Compliance Policy Guide § 120.500.

indirect health risk when a consumer relies on a Health Fraud in delaying or discontinuing appropriate medical treatment. *Id.*

The FDA has, on many occasions, issued Warning Letters to dietary supplement manufacturers for perpetrating Health Frauds in marketing their supplements as able to cure or mitigate diseases. *See* https://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/ucm255474.htm (identifying dozens of Warning Letters sent on dietary supplements classified as "New Drugs" or "Unapproved New Drugs" as a result of their labeling since 2007). Warning letters such as these "communicate[] the agency's position on a matter" and "are issued only for violations of regulatory significance." FDA, Regulatory Procedures Manual § 4-1-1 (last updated Oct. 22, 2015), available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm ("[t]he agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected.") Based on the time and energy the FDA has committed to combatting Health Fraud, it is obviously an important matter for consumer protection.

II. GNC'S HEALTH FRAUD

While dietary supplements cannot claim to treat or mitigate a disease or disease condition, they can make structure/function claims which describe the effect a dietary supplement may have on the structure or function of the body. 21 C.F.R. § 101.93(f). Permitted structure/function claims are statements, "that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims." *Id.* Of course, a company labeling a dietary supplement with a structure/function claim must have substantiation that the statement is truthful and not misleading. Id. at 101.93(a)(3). Whether a claim is a disease claim or a structure/function claim is determined based on the objective evidence in the labeling of the product, and whether the claim explicitly or implicitly is a disease claim (e.g., the claim may not mention a disease by name but may refer to identifiable characteristic signs or symptoms of a disease and that such intended use of the product to treat or prevent disease is inferred). *See* FDA Guidance of Industry: Structure/Function Claims, Small Entity Compliance Guide (hereafter "FDA Small Entity Compliance Guide"), topic D available online at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm103340.htm.

Products that expressly or impliedly claim to mitigate, treat, cure, or prevent disease are "new drugs" under the FDCA. 21 U.S.C. § 321(p). New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA. 21 U.S.C. § 355(a); *see also* 21 U.S.C. § 331(d). The FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. In addition, many conditions, including some claimed on the labeling of the Supplements, are not amenable to self-diagnosis and treatment by typical consumers (who are not medical practitioners); therefore, adequate directions for their use cannot be written so that a layperson can use these drugs safely for their intended purposes, and they cannot be marked as over-the-counter ("OTC") drugs.

21 U.S.C. § 352(f)(1). The introduction of a misbranded drug into interstate commerce is a violation of the FDCA. 21 U.S.C. § 331(a). Under federal and parallel states' laws, when a company markets a dietary supplement as treating or preventing diseases, the product is classified as a drug. In the marketing and sales of the Supplements, GNC has perpetrated a Health Fraud by promoting the Supplements as drugs, able to prevent, cure, treat, or mitigate disease, or augment drug therapies, and it has done so as follows:

A. GNC Healthy Cholesterol Formula, GNC Policosanol, GNC Ultra 35 Probiotic Complex, and GNC Probiotic Solutions Adults 50 Plus Each Implicitly Claim to Treat or Mitigate Hypercholesteremia

Certain GNC dietary supplements claim to support healthy cholesterol levels. *See* Exh. 1 (GNC Healthy Cholesterol claiming that it "Supports Normal, Healthy Cholesterol & Triglyceride Levels."); Exh. 2 (GNC Policosanol (200 mg) claiming that it "May help to maintain normal, healthy cholesterol levels"); Exh. 3 (GNC Ultra 35 Probiotic Complex claiming to be "Cholesterol support" and "Clinically studied support for healthy cholesterol levels"); Exh. 4 (GNC Probiotic Solutions Adults 50 Plus claiming that it "May support healthy cholesterol … levels"); Exh. 5 (GNC Women's Ultra Mega 50 Plus (Vitapak) claiming that it "promotes healthy cholesterol … levels"); Exh. 6 (GNC Women's Ultra Mega Menopause claiming that it "[s]upports heart and cholesterol health with omega-3s."). A claim that a dietary supplement can "support healthy cholesterol levels" that does not also expressly state that the supplement can only maintain already normal cholesterol levels is an illegal disease claim because it suggests that the supplement can be used to treat or mitigate hypercholesteremia.

In implementing the Final Rule to 21 C.F.R. 101.93, the FDA discussed statements that would be considered disease claims by explicitly or implicitly claiming an effect on one or more signs or symptoms that are recognizable to consumers as being characteristic of a specific disease. 65 Fed. Reg. 1000-01, 1015 (Jan. 6, 2000) (to be codified at 21 C.F.R. Part 101). The FDA noted that in its earlier notices about structure/function claims, claims related to maintaining healthy cholesterol levels raised particularly difficult issues for the FDA because of its obvious link to coronary heart disease in consumers' minds. *Id.* After considering a large number of public comments on this issue, the FDA concluded that claims concerning the maintenance of a normal cholesterol level does not implicate a disease because a cholesterol level within the normal range is not a sign or risk factor for disease, and maintaining cholesterol levels within the normal range is essential to the structure and function of the body for reasons other than prevention of heart disease. *Id.* at 1018. However, the FDA also determined that claims about cholesterol that go beyond maintaining levels that are already within the normal range would explicitly or implicitly claim to be treating heart disease. *Id.* at 1019 (giving examples such as "lowers cholesterol" and "promotes cholesterol clearance"). Indeed, despite the Surgeon General of the United States commenting that dietary supplements should be permitted to make claims for cholesterol reduction due to the prevalence of heart disease in the United States, the FDA concluded that such claims are prohibited on dietary supplements because "use of possibly ineffective therapies in persons with elevated cholesterol, which can delay or prevent effective treatment, poses significant public health risks." *Id.*

To avoid this risk, a structure/function claim for cholesterol maintenance "must explicitly disclaim the implied ability of the product to prevent the development of elevated cholesterol levels or to reduce an elevated cholesterol" in order to avoid the misconception that it can treat or mitigate a disease. *See* Letter to Dennis M. Gronek, Esq. dated May 1, 2000 available online at https://www.fda.gov/ohrms/dockets/dailys/01/Jun01/061101/let0486.pdf. *See also* FDA Warning Letter to Premier Direct, Inc. (May 1, 2001) available at https://www.fda.gov/ohrms/dockets/dailys/01/Jun01/061101/let0486.pdf ("an appropriate structure/function claim about maintaining cholesterol should explicitly state the cholesterol levels that are the subject of the claim are 'already within the normal range. … We do not believe that the meaning of 'to maintain normal' conveys the same meaning as 'maintain levels that are already normal'"); *also* FDA Response to Mark W. Rollinson regarding Kendy USA LLC products available at https://www.fda.gov/ohrms/dockets/dailys/04/aug04/080204/97s-0163-let00763-vol23.pdf (same). As your Supplements containing the cholesterol claims above do not make clear that they can only support or maintain cholesterol levels that are ***already*** normal, they are misleading and misbranded in violation of federal and states' laws as explained in Section VI, *infra*.

B. GNC Healthy Blood Sugar Formula Implicitly Claims to Treat or Mitigate Abnormal Blood Glucose Levels

GNC Healthy Blood Sugar Formula claims to "support normal, healthy blood glucose levels." *See* Exh. 7. This is an illegal disease claim, regardless of whether it is true. *See* FDA Warning Letter to Premier Direct ("we consider the claims 'maintain cholesterol levels within a normal range,' 'maintain blood pressure levels within a normal range,' and 'maintain blood sugar levels within a normal range' to be implied claims to treat, prevent, cure, or mitigate diseases, namely, hypercholesteremia, hypertension, and abnormal blood glucose levels"). In responding to Premier Direct's questions about the appropriateness of its "maintain blood sugar levels within a normal range," the FDA explained that much like cholesterol, consumers view such a claim as implying that the product can help lower blood sugar levels, or prevent the development of elevated blood sugar levels, similar to how consumers view cholesterol claims. *See* Letter to Dennis M. Gronek, *supra*. Thus, any claim about supporting or maintaining blood glucose levels must explicitly disclaim the implied ability to prevent or mitigate abnormal blood glucose levels by indicating it can maintain blood sugar levels that are ***already*** within a normal range. *Id.* As the Supplement identified above does not make it clear that they can only support or maintain blood sugar levels that are ***already*** normal, it is misleading and misbranded in violation of federal and states' laws. *See* Section VI, *infra*.

C. GNC Healthy Cholesterol and Healthy Blood Sugar Formula Explicitly Claim to Act as Anti-Inflammatory Drugs

Certain Supplements claim to act as anti-inflammatory drugs. *See* Exh. 1 (GNC Healthy Cholesterol claims that it contains an "Inflammatory Response Support Blend"); Exh. 7 (GNC Healthy Blood Sugar Formula claims that it "supports a healthy inflammatory response.") The FDA has indicated that a claim in dietary supplement labeling that the product "supports inflammatory response" is a disease claim. *See* FDA Warning Letter to Michelle's Miracle, Inc. (June 8, 2012) available online at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm307676.htm.

That a product claiming to be an anti-inflammatory is a drug should be obvious. Inflammation is not the body's normal condition (i.e., structure or function); rather, it is a body's response to a variety of disease processes linked with the immune system for which the FDA has approved numerous drugs. *See, e.g.,* M.S. Kinch and Merkel, J., An analysis of FDA-approved drugs for inflammation and autoimmune diseases. Drug Discovery Today, 2015 Aug;20(8):920-3 (February 17, 2015). Given that supporting an "inflammatory response" is a statement to mitigate, treat, cure, or prevent disease, the Supplements identified above are misleading and misbranded in violation of federal and states' laws as explained *infra*.

D. GNC Women's Ultra Mega Vitapak, Healthy Blood Pressure Formula, Pycnogenol, Quercetin, Selenium, Zinc, and Women's Ultra Mega 50 Plus Each Explicitly or Implicitly Claim to Treat or Mitigate Oxidative Stress

The following Supplements claim to protect against free radical damage:

- GNC Women's Ultra Mega Vitapak ("helps protect against harmful free radicals that can destroy healthy cells and promote the cell aging process") at Exh. 5.
- Pycnogenol ("protects cells from free radical damage") at Exh. 9;
- Quercetin ("protects against free radical damage") at Exh. 10;
- Selenium ("helps fight cell-damaging free radicals") at Exh. 11; and
- Zinc ("protect cells against the damage caused by free radicals") at Exh. 12.

A claim that a product can protect the body from damage from free radicals is a disease claim. *See, e.g.*, FDA Warning Letter to Juve International LLC dated April 2, 2013 available online at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351265.htm (the claim "[f]ruits such as the superfruit Maqui berry (an ingredient in your product) have the ability to take up free radicals that cause cellular damage that may lead to disease" is a drug claim); FDA Warning Letter dated March 2, 2017 to Cape Fear Naturals, LLC, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm545773.htm ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … Beta Carotene capsules "[S]tops free radical damage…"); FDA Warning Letter dated May 19, 2015 to CK Management, Inc., http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm448810.htm (claims that antioxidants reduce and/or eliminate free radicals is a disease claim meaning that the antioxidants are intended to be used as drugs).

Claims that a product can treat or prevent free radicals are disease claims within the meaning of the FDCA because the body does not normally have excessive free radicals. When free radicals overwhelm the body's ability to regulate them, a condition known as oxidative stress ensues, which can adversely alter lipids, proteins and DNA. *See* V. Lobo, *et al.* Free Radicals, antioxidants and functional foods: Impact on human health. Pharmacogn Rev. 2010 Jul-Dec; 4(8): 118–126. This in turn may potentially trigger a number of diseases or disease conditions, including inflammatory diseases, ischemic diseases, neurological disorders, and many others. *Id.* Given that the Supplements' "free radical" claims explicitly or implicitly claim to treat or mitigate oxidative

stress and/or all of the potential conditions that could result from oxidative stress, they are misleading and unlawful in violation of federal and states' laws for the reasons explained *infra*.

E. GNC Ultra Zinc Lozenges Explicitly or Implicitly Claims to Fight Disease

GNC Ultra Zinc Lozenges claim to "help support natural resistance." *See* Exh. 12. A claim that a dietary supplement may help support the immune system is a lawful structure/function claim because the immune system is involved in more than just fighting off diseases. 65 Fed. Reg. at 1029. However, a claim that a dietary supplement can help fight disease or enhance disease-fighting functions is a disease claim, as such claims express or imply that the product can help prevent disease. *Id. See also* 63 Fed. Reg. 23624-01, 23627 (explaining that a claim that a dietary supplement can help resist infection is a drug claim because infections are well-known disease states that result from the action of pathogenic microorganisms, and are deviations from and impairments of the normal structure and/or function of the body). Because the only reasonable interpretation for "support natural resistance" is to support the body's resistance to disease, it is an illegal disease claim and not a structure/function claim. *See also* FDA Warning Letter to Vitamins Direct (USA), Inc. (October 17, 2014) ("can help build the body's natural resistance" is a disease claim). Accordingly, GNC's Supplements labeled as supporting natural resistance are misleading and misbranded in violation of federal and states' laws as explained *infra*.

F. GNC CoQ-10 (100 mg, 200 mg and 400 mg) Explicitly or Implicitly Claim to Augment Statin Therapy

GNC claims that each of its CoQ-10 Supplements "Helps replenish CoQ-10 levels reduced by statin drugs," "Clinically shown to support heart health" and sometimes "Powerful cardiovascular antioxidant." *See* Exhs. 13, 14, and 15. A claim that a dietary supplement can augment a therapy or drug intended to diagnose, mitigate, treat, cure or prevent a disease is a disease claim. 21 C.F.R. § 101.93(g)(2)(vii). While indicating CoQ-10 supplements can replenish CoQ-10 levels reduced by statin therapy might be an acceptable claim for a dietary supplement (*see* Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide – Criterion 9 available online at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm103340.htm), when it is combined with mentioning the name of a specific therapy, drug or drug action it will cause the claim to be a disease claim. *Id.* at Criterion 7. Here, GNC combines replenishment of CoQ-10 with statin drug therapy which are commonly recognized as drugs which lower cholesterol for the purpose of fighting cardiovascular disease. See Controlling Cholesterol with Statins online at https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm293330.htm. Indeed, the FDA has indicated that claiming CoQ-10 supplements can help replenish levels after taking statin drugs is a therapeutic drug claim. *See, e.g.*, FDA Warning Letter to Golden Cavier Skin Care dated July 13, 2015 available online at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm456547.htm indicating that the claim, "Evidence suggests people who take statin drugs to treat high cholesterol levels may be simultaneously depleting their CoQ10 levels. Many cardiologists are now recommending CoQ10 to patients as an adjunct to traditional medical treatments" indicates a dietary supplement is intended to be used as a drug. Moreover, the inclusion of the claims they the CoQ-10 Supplements "support heart health" and are "powerful cardiovascular antioxidant" implies that they can help fight cardiovascular disease which, again,

is a disease claim. Accordingly, GNC's CoQ-10 Supplements are misleading and misbranded in violation of federal and states' laws as explained *infra*.

G. GNC Women's Ultra Mega 50 Plus and Women's Ultra Mega Menopause Explicitly or Implicitly Claim to Treat or Mitigate Osteoporosis

GNC Women's Ultra Mega 50 Plus (individual bottles and Vitapaks) claims to support "Bone Health" and Ultra Mega Menopause claims that it "helps build and maintain bone density." *See* Exhs. 5, 6, and 16. A statement linking a dietary supplement to "bone health" can be an appropriate structure/function claim if the claim does not imply that the product can treat a disease or condition such as osteoporosis. *See* 65 Fed. Reg. at 1019. However, when a statement about "bone health" or "maintain bone density" is combined with an express or implied claim about menopause, including targeting the statement towards post-menopausal women, it is a disease claim because "post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass." *Id. See also id.* at 1013 (consumers easily understand that "bone fragility in post-menopausal women" is conveying treatment for osteoporosis); *id* at 1018 ("a claim to 'maintain normal bone density in post-menopausal women' is a disease claim because post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass.") Critically, the FDA (and consumers) look at the labeling of a product as a whole, including the name of the product, to determine if the product is being promoted to treat a disease, or whether it is truly a claim about the structure or function of the body. *Id.* at 1022.

Your "bone health" and "bone density" Supplements target menopausal women directly and indirectly by being labeled for women over fifty years old, a population commonly known to be at heightened risk of developing osteoporosis. *See* FDA Small Entity Compliance Guide (some natural processes such as menopause are not themselves diseases, but can be associated with abnormal conditions that are diseases); 65 Fed. Reg. at 1017 ("post-menopausal women characteristically develop osteoporosis"). Reference to menopausal women and women over 50 strongly implies that the bone health claims on your product are intended to mitigate or prevent osteoporosis in post-menopausal women. *See id.* at 1018 ("In some cases, a health maintenance claim could use terms that...so clearly refer to a particular at-risk population that FDA would consider the claim to be an implied disease prevention claim.") As GNC's "bone health" and "maintain bone density" claims are on Supplements targeted towards post-menopausal women, they imply the Supplements can mitigate or prevent osteoporosis and are disease claims in violation of federal and states' laws as explained *infra*.

III. THE FDA HAS STATED THE CLAIMS ABOVE ARE UNAPPROVED DRUG CLAIMS

It is clear that GNC is marketing the Supplements as being able to treat or mitigate various diseases or disease states, making the Supplements unauthorized drugs. *See* 21 C.F.R. § 321(g)(1)(C). As the FDA said in the identified and other similar Warning Letters, claims such as the ones quoted above establish that the Supplements are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. Yet, GNC's Supplements are not generally recognized as safe and effective for the above referenced uses and, therefore, they are "new drugs" under 21 U.S.C. § 321(p). New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA. 21 U.S.C.

§ 331(d), 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective for its marketed purpose. See "How FDA Evaluates Regulated Products: Drugs" available online at https://www.fda.gov/AboutFDA/Transparency/Basics/ucm269834.htm.

A court would afford substantial deference to the FDA's interpretations of applicable regulations as communicated in warning letters, agency opinion letters, and compliance policy guides. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000) (FDA is entitled to deference when it interprets Title 21 of the United States Code); *Cmty. Health Ctr. v. Wilson–Coker*, 311 F.3d 132, 138 (2d Cir.2002) ("[E]ven relatively informal [agency] interpretations, such as letters from regional administrators, warrant respectful consideration" where the statute at issue is complex and the regulatory agency possesses "considerable expertise") (citations and quotations omitted); *Reid v. Johnson & Johnson*, 780 F.3d 952, 962 & 967 (9th Cir. 2015) (*citing Auer v. Robbins*, 519 U.S. 452, 461 (1997)) (reversing district court's dismissal of food-labeling class action lawsuit based, in part, on inadequate deference to FDA guidance articulated in warning letters); *see also Bassiri v. Xerox Corp.*, 463 F.3d 927, 930 (9th Cir. 2006) (granting *Auer* deference to agency opinion letters); *L.A. Closeout, Inc. v. Dept. of Homeland Sec.*, 513 F.3d 940, 941-42 (9th Cir. 2008) (granting *Auer* deference to an agency's "internal memorandum"); *In re Establishment Inspection of: Wedgewood Vill. Pharmacy, Inc.*, 270 F. Supp. 2d 525, 549 (D.N.J. 2003), subsequently aff'd sub nom. *Wedgewood Vill. Pharmacy, Inc. v. United States*, 421 F.3d 263 (3d Cir. 2005) (giving *Chevron* deference to FDA's interpretation of regulations concerning drug compounding as stated in a Compliance Policy Guide); *United States v. An Article of Device Consisting of 1,217 Cardboard Boxes*, 607 F. Supp. 990, 995 (W.D. Mich. 1985) (a letter from the FDA explaining its interpretation of a regulation that was consistent with its compliance policy guide was "accorded substantial deference" by the Court). For this reason, we are confident a court would find the Supplements' Unapproved Drug Claims are material not only to our Clients, but to consumers generally.

IV. THE SUPPLEMENTS' LABELS ARE FALSE AND MISLEADING IF THE SUPPLEMENTS ARE NOT EFFECTIVE

It should go without saying that if GNC's Supplements are not able to provide the labeled therapeutic benefits, then the labeled therapeutic benefits are false and misleading in violation of federal, California and New York laws. *See* 21 U.S.C. § 343(a) (a food is misbranded "if its labeling is false or misleading in any particular"); Sherman Law, § 110660 (same). As explained in Section V, *infra*, such false and misleading labeling is also a violation of California and New York consumer protection laws.

V. THE SUPPLEMENTS' LABELS ARE MATERIALLY MISLEADING EVEN IF THE SUPPLEMENTS ARE SAFE AND EFFECTIVE

GNC may defend the use of the Supplements' unapproved drug claims by arguing that they are safe and effective at providing the advertised therapeutic benefits. Assuming GNC has sufficient scientific data and information to demonstrate that the Supplements are safe and effective for their currently marketed purposes so that they could be approved by the FDA as new drugs – a point our Clients do not concede – then the current labeling is materially misleading to consumers because it omits many facts the FDA has deemed material for drugs marketed in the

U.S, and has not presented the required information in a way to make it easily understood by consumers. Thus, whether the Supplements safely and effectively convey the advertised therapeutic benefits is irrelevant to whether the current labeling is misleading. The current labeling is materially misleading either because the Supplements are not safe and effective for the labeled unapproved Disease Claims or, if safe and effective for those claims, the Supplements' labels fail to make the FDA required drug fact disclosures which are material as describe below. Either way, the currently labeling of the Supplements with the Disease Claims is unlawful, misleading and cannot continue to be labelled and marketed as is. GNC can rectify the problem by removing the Disease Claims from the Supplements' labeling, modifying the Supplements' labeling to change the Disease Claims into appropriate structure/function claims, or, as explained below, GNC must receive approval of the Disease Claims and add the drug fact disclosures to the Supplements' labels conforming to federal regulations.

Congress charged the FDA with ensuring that drugs are not only safe and effective, but also that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading.

> Under the act and FDA regulations, the agency makes approval decisions based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance. The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate.

71 Fed. Reg. 3922, 3934 (January 24, 2006).

Amongst other things, prescription drug labeling must include:

- Highlights of prescribing information that includes the dosage; concise summary of any boxed warnings; indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; and adverse reactions.

- Full Prescribing information with appropriate headings and subheadings that detail any boxed warnings; indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; adverse reactions; drug interactions; use in specific populations, pregnancy risks; effects on reproductive potential; pediatric use; geriatric use; description including chemical and physical information; clinical pharmacology; nonclinical toxicology; clinical studies; references; proper storage and handling; patient counseling information.

See 21 C.F.R. § 201.57 (a) – (c). Critically, this information must be printed in accordance with a specific format and with minimal type size requirements for the ease of reading and understanding by a physician and patient. 21 C.F.R. § 201.57(d).

The FDA has specific requirements for uniform labeling for over-the-counter (OTC) drugs, which the Supplements could be classified as. Amongst other things, OTC drug product labeling must include:

- A Title "Drug Facts" with a specific graphical design to be a visual cue to consumers for introducing required information. 21 C.F.R. § 201.66(c)(1).

- Active Ingredients with the established name and quantity or proportion of each active ingredient (21 C.F.R. § 201.66(c)(2)) placed immediately below a prominent title to enable consumers to quickly and systematically compare ingredient within products for similar uses. 64 Fed. Reg. 13254-01, 13260.

- Purposes to describe the principal intended actions of the drug or each active ingredient. 21 C.F.R. § 201.66(c)(3).

- Uses to provide the indications for use of the product. 21 C.F.R. § 201.66(c)(4).

- Warnings with specific information and subheadings including whether the product is for external use only and, as appropriate, for rectal or vaginal use; Reye's syndrome warning if the product contains salicylates; allergic reaction and asthma alert warnings; contraindications when consumers should not use the product unless a doctor directs the usage; preexisting conditions warnings; juvenile warnings; pregnancy warnings; accidental ingestion/overdose warning. 21 C.F.R. § 201.66(c)(5).

- Directions for use. 21 C.F.R. § 201.66(c)(6).

- Other Information required by the FDA specifically excluding any promotional material as it is generally not necessary for the safe and effective use of the product. 21 C.F.R. § 201.66(c)(7) and 64 Fed. Reg. 13254-01, 13263.

- Inactive Ingredients in accordance with 21 C.F.R. § 201.66(c)(8).

- Questions or Comments providing the telephone number of a source to answer questions about the product. 21 C.F.R. § 201.66(c)(9).

This required information on OTC drug labels must also be in specific, uniform placement and format including the alignment and punctuation of headings, type size, font, contrast, highlighting, graphical images, etc. 21 C.F.R. § 201.66(d).

GNC's Supplements with unapproved Disease Claims detailed above contain none of the required labeling of prescription or OTC drugs. This failure to label the Supplements with the required information for prescription or OTC drugs is material to consumers who either rely on medical professionals to be able to recommend the best drug for their needs, or are accustomed to reviewing information about OTC drugs themselves to self-select the best OTC product for their own needs.

A. Required Prescription Drug Labeling is Material to Consumers

If the FDA approved GNC's Supplements as prescription drugs, the labels omit important dosage, warnings, indications, administration, contraindications, warnings, precautions and adverse reactions to help inform both a consumer and a consumer's doctor about the appropriate use of the products. Even though prescription drug labeling is designed for health care practitioners, without this information presented in an easy-to-read and uniform manner, health care practitioners cannot find and discern the most critical information in deciding whether to recommend the drug to a patient. 71 Fed. Reg. 3922. Consumers rely on their health care practitioners to have all of the critical information about a drug when recommending a drug for a specific purpose, and if the information is not both present and in the required easy-to-read format, consumers will be harmed.

B. Required OTC Drug Labeling is Material to Consumers

If the FDA approved GNC's Supplements as OTC drugs, the current labels omit information important to consumers about the active ingredient(s), the purpose, uses, warnings, and directions of use of the Supplements. This information required for approved drugs normally allows consumers to know what is providing the advertised therapeutic benefits, how much of the active ingredient is in the product, how much of the product must be used to achieve the advertised therapeutic benefits, whether there are any potential side effects and whether the consumer should avoid using the product (such as if they are pregnant). This information is material to consumers who wish to make an educated decision not only about what drugs they are putting in their bodies, but also whether it is the best and/or most economical product for what they are trying to accomplish.

The Supplements also fail to provide required information in the uniform manner which all OTC drugs must use. Having the information presented in an easy-to-read and uniform format is nearly as important as providing the underlying information itself. In implementing the regulations for uniform OTC drug labeling, the FDA determined that non-uniform labeling of OTC drugs prevented consumers from being able to choose between similar products, which led to consumer confusion. 64 Fed. Reg. 13254-01. After conducting consumer studies and receiving more than 1,800 comments regarding the need for uniform OTC drug labels, the FDA concluded that the standardized format and content requirements in its OTC drug products labeling regulations would enable consumers to better read and understand the information represented,

apply the information to the safe and effective use of OTC drug products, and compare products with similar uses. *Id.* at 13254-55. The FDA also concluded that having the information on OTC drug products presented pursuant to its regulations "most closely tracks a logical decision making process that would allow for the best selection and best use of OTC drug products." *Id.* at 13259. Presenting OTC drug information in a uniform way that tracks consumers logical decision-making has three critical benefits: (1) it enhances the therapeutic value of OTC drug products by helping consumers select appropriate products and adhere to proper dosage regimens; (2) consumers find it easier to avoid ingredients or products that in some circumstances cause adverse events such as allergic reactions, adverse drug interactions, or other unintended outcomes, ranging from minor discomfort to hospitalization; and (3) consumers will increase the economic efficiency of their OTC drug purchases by more quickly locating and identifying key elements of product information, such as appropriate ingredients, uses, and warnings. *Id.* at 13277.

GNC does not provide the required Drug Facts for its Supplements, and does not provide the information to allow consumers to identify key elements of product information so that they can evaluate and purchase the best product for their therapeutic needs. As the FDA concluded in implementing its uniform OTC drug labeling regulations, presenting certain information and in a consistent, uniform manner across all OTC drugs is material for consumers in deciding what medicines to purchase for conditions appropriate for self-diagnosis and treatment.

Without having gone through the NDA process, GNC's advertising the Supplements with the above-detailed Disease Claims renders the Supplements misbranded under federal and states' laws as more fully described below. Moreover, given that GNC's Supplements as currently-labeled are unapproved drugs, it is misleading to market them as dietary supplements, or to include treatment, cure, disease prevention, and/or mitigation claims in its labeling as the products do. This advertising violates New York and California laws. Without having gone through the NDA process, GNC simply cannot market its Supplements as impliedly or expressly treating or mitigating disease or disease conditions, and continuing to do so is a Health Fraud and a major economic cheat. *See* FDA Compliance Policy Guide § 120.500 Health Fraud.

VI. VIOLATIONS OF NEW YORK AND CALIFORNIA LAW

Without having gone through the NDA process, GNC's sale of the Supplements with the above-described Disease Claims renders them illegal under federal and states' laws. *See* 21 U.S.C. § 331(d) and 355(a) (new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA); New York Education Law § 6817.1 (same); Cal. Health & Safety Code § 111550 (same). Moreover, GNC's failure to get new drug approval from the FDA, and marketing the products as dietary supplements with unlawful drug claims while omitting material disclosures required for all drugs is misleading in violation of identical federal, New York and California laws. 21 U.S.C. §§ 352(a) and 343(a) (a drug or food is misbranded if its labeling is false or misleading in any particular); Cal. Health Safety Code §§ 111330 and 110660 (same); New York Education Law §§ 6815.2(a) (drugs are misbranded if the labeling is false or misleading). As a result of GNC's introduction of the Supplements bearing Disease Claims into interstate commerce without prior approval as new drugs, GNC sold the Supplements to many thousands of consumers in New York, California and throughout the United States, generating substantial profits for itself in turn.

In addition to the violations above, GNC's labeling of the Supplements in the ways described above violates both New York and California consumer laws, separate and apart from its violations of the FDCA. In violation of the CLRA, Cal. Civ. Code § 1770(a)(2), GNC misrepresented the Supplements as dietary supplements when they were actually unapproved drugs, and that the advertised claims were structure/function claims when they were actually drug claims that were required to be evaluated and approved as safe and effective for the advertised purposes by the FDA prior to being included in the labeling use and the attendant FDA required drug fact disclosures were required to be provided to consumers on the Supplements' labeling; in violation of § 1770(a)(5) that the Supplements were represented to have the approval, uses and/or benefits they do not have because they are not proven safe and effective for the advertised uses or benefits; and in violation of § 1770(a)(7) that the Supplements were represented to be of a particular standard, quality or grade, *i.e.*, as dietary supplements, when they are unapproved drugs. GNC's same conduct also gives rise to claims under New York General Business Laws prohibiting False Advertising and Deceptive Acts or Practices, New York Gen. Bus. Law §§ 349 and 350[4], claims for breach of express and/or implied warranties, under common law for unjust enrichment, fraudulent concealment and nondisclosure, and other statutory and common law claims.

VII. DEMAND FOR RELIEF

In accord with Cal. Civ. Code § 1782, New York law, and any other laws requiring pre-suit demand and notice,[5] our Clients demand that within thirty (30) days of receipt of this letter, GNC take the following steps to cure the issues complained of herein:

1. Provide our Clients an accounting of your sales and profits (both gross and net profits) for Supplements sold within the past four (4) years in New York and California which were labeled in violation of applicable laws and regulations in any of the ways described above;

2. Refrain from selling in California and New York Supplements mislabeled in any of the ways described above, in violation of applicable laws and regulations; and

3. Pay damages and restitution to our Clients, and to all other putative class members in California and New York, as well as attorneys' fees and expenses.

If we do not receive a response from you within thirty (30) days of receipt of this letter, we will assume that GNC has no interest in curing the matters complained of herein, and one or more of our Clients may file a complaint seeking damages and/or injunctive or equitable relief for themselves and similarly situated persons for GNC's violations of federal and state law.

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[4] Moreover, New York Gen. Bus. Law § 349(h) provides for the recovery of "actual damages or fifty dollars, whichever is greater," and § 350-E(3) provides for the recovery of "actual damages or $500, whichever is greater."

[5] This notice and demand is meant to comply with all states' laws in the United States requiring a pre-suit demand and notice on behalf of our Clients and any additional plaintiff(s) and class members should this matter proceed to litigation.

Thank you for your attention to this matter. If you wish to discuss this matter, please contact Joseph N. Kravec, Jr., the lead counsel on this matter, in my office at 412-281-8400.

Sincerely,

William T. Payne

William T. Payne
Admitted in CA and PA

Joseph N. Kravec, Jr.
Admitted in PA and NY

Enclosures

cc: Mr. Howard Clark (via Electronic Mail w/o enclosures)
Ms. Christina Labajo (via Electronic Mail w/o enclosures)
Ms. Marcia Nupp (via Electronic Mail w/o enclosures)
Jason Adkins, Esquire (Admitted in MA) (via Electronic Mail)
John Peter Zavez, Esquire (Admitted in MA) (via Electronic Mail)

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Ken Martindale
Chief Executive Officer
GNC Holdings, Inc.
300 Sixth Avenue
Pittsburgh, PA 15222

9590 9402 2250 6225 2032 45

2. Artic... (Transfer from service label)

7017 0660 0000 7491 9265

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X

☐ Agent
☐ Addressee

B. Received by (Printed Name)

C. Date of Delivery
11-2017

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☐ Adult Signature
☐ Adult Signature Restricted Delivery
☐ Certified Mail®
☐ Certified Mail Restricted Delivery
☐ Collect on Delivery
☐ Collect on Delivery Restricted Delivery
☐ Priority Mail Express®
☐ Registered Mail™
☐ Registered Mail Restricted Delivery
☐ Return Receipt for Merchandise
☐ Signature Confirmation™
☐ Signature Confirmation Restricted Delivery

...cted Delivery

PS Form 3811, July 2015 PSN 7530-02-000-9053

Domestic Return Receipt

SENDER: *COMPLETE THIS SECTION*

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Ken Martindale, CEO
General Nutrition Corporation
c/o National Registered Agents, Inc.
818 West Seventh Street - Suite 930
Los Angeles, California 90017

9590 9402 2250 6225 2032 38

2. Article Number *(Transfer from service label)*

7017 0660 0000 7491 9272

COMPLETE THIS SECTION ON DELIVERY

A. Signature

CT CORPORATION SYSTEM
X 818 West Seventh Street
Suite 930
Los Angeles, CA 90017

☐ Agent
☐ Addressee

B. Received by *(Printed Name)*

C. Date of Delivery
NOV 21 2017

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type

- ☐ Adult Signature
- ☐ Adult Signature Restricted Delivery
- ☐ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery
- ☐ Priority Mail Express®
- ☐ Registered Mail™
- ☐ Registered Mail Restricted Delivery
- ☐ Return Receipt for Merchandise
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

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PS Form 3811, July 2015 PSN 7530-02-000-9053 Domestic Return Receipt

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429 Fourth Avenue
Law & Finance Building, Suite 1300
Pittsburgh, PA 15219